# "COMPARATIVE EVALUATION OF BEHAVIOR, ANXIETY, PULSE RATE AND PAIN PERCEPTION IN CHILDREN USING TWO LOCAL ANESTHESIA DELIVERY SYSTEMS – A RANDOMIZED CONTROLLED TRIAL"

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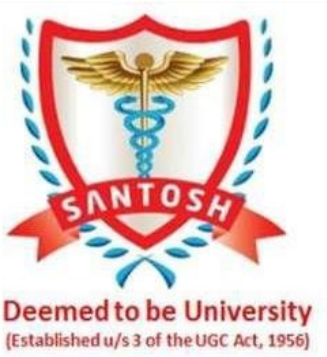
**SANTOSH UNIVERSITY, GHAZIABAD, NCR DELHI**

In partial fulfillment of the requirement for the degree of

**MASTER OF DENTAL SURGERY**

in the Specialty of

**PEDIATRIC AND PREVENTIVE DENTISTRY**

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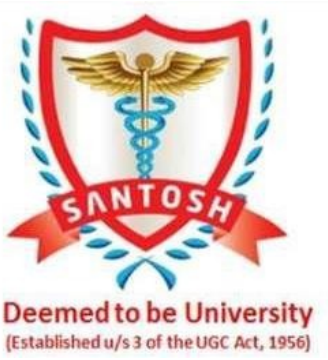


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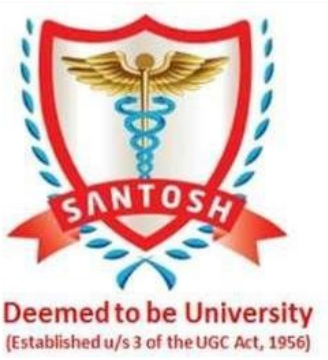


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*Dedicated to all*

***My Beloved Teachers,***

***My Family***

***My Friends***

*For supporting me in all aspects which I have been through in these years*

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**Dr. Sonam Yadav**

## TABLE OF CONTENTS


| *S. No* | *Title* | *Page No.* |
|---|---|---|
| **1.** | Introduction | **1** |
| **2.** | Aims and Objectives | **7** |
| **3.** | Review of Literature | **8** |
| **4.** | Materials and Method | **41** |
| **5.** | Color Plates | **49** |
| **6.** | Statistical Analysis | **56** |
| **7.** | Results | **58** |
| **8.** | Discussion | **71** |
| **9.** | Summary and Conclusion | **79** |
| **10.** | Limitation of the Study | **81** |
| **11.** | Scope of the Study | **82** |
| **12.** | Bibliography | **83** |
| **13.** | Annexures | **92** |

# LIST OF COLOR PLATES


| *Colour plate no.* | *Figure no.* | *Title* | *Page No.* |
|---|---|---|---|
| **1.** | **1.** | Local Anesthesia (Lignox 2% A, Indoco Warren, India) | **49** |
| | **2.** | Tropical Anesthetic Gel (Lignospan-O, Septodont Healthcare India Pvt. Ltd.) | **49** |
| | **3.** | Local Anesthetic Cartridge (Lignospan Special-Septodont) | **50** |
| | **4.** | Pulse-oximeter (AmbiTech, Phoenix Innovative Healthcare Manufactures Pvt. Ltd.) | **50** |
| | **5.** | 2ml Conventional Syringe with 24G needle (Shinrai, NIPRO Single-use Syringe) | **50** |
| | **6.** | StarPen Anesthetic Pen (Guilin Woodpecker Medical Instrument Co., Ltd., P.R.China) | **51** |
| | **7.** | Vibraject (A. Titan, Miltex LIC., York, PA, USA) | **52** |
| **2** | **8.** | Administration of Inferior Alveolar Nerve Block using StarPen | **53** |
| | **9.** | Administration of Inferior Alveolar Nerve Block using Vibraject | **54** |
| | **10.** | Administration of Inferior Alveolar Nerve Block using Conventional Syringe | **55** |

# LIST OF TABLES


| *Table No.* | *Title* | *Page No.* |
|---|---|---|
| **Table no. 1** | Assessment of Behavior using Frankl's Behavior Rating Scale | **45** |
| **Table no. 2** | Assessment of Anxiety using Venham's Anxiety Scale | **46** |
| **Table no. 3** | Assessment of Pain using Face, Legs, Activity, Cry, Consolability (FLACC) Scale | **47** |
| **Flow chart 1** | A diagrammatic representation of the trial according to CONSORT | **48** |
| **Table no. 4** | Mean FLACC score during treatment | **58** |
| **Table no. 5** | Mean Venham's Anxiety scale before treatment | **59** |
| **Table no. 6** | Mean Venham's anxiety scale during treatment | **61** |
| **Table no. 7** | Mean change in venham's anxiety levels before and during treatment | **62** |
| **Table no. 8** | Mean Pulse rate before treatment | **63** |
| **Table no. 9** | Mean Pulse rate during treatment | **64** |
| **Table no. 10** | Mean change in pulse rate before and during treatment | **66** |
| **Table no. 11** | Mean Frankl Behaviour rating before treatment | **67** |
| **Table no. 12** | Mean Frankl behaviour rating scale after treatment | **68** |
| **Table no. 13** | Mean change in Frankl behaviour rating before and after treatment | **69** |

# LIST OF GRAPHS


| *Graph No.* | *Title* | *Page No.* |
|---|---|---|
| **Graph No. 1** | Mean FLACC score during treatment | **59** |
| **Graph No. 2** | Mean Venham's Anxiety scale before treatment | **60** |
| **Graph No. 3** | Mean Venham's anxiety scale during treatment | **61** |
| **Graph No. 4** | Mean change in venham's anxiety levels before and during treatment | **62** |
| **Graph No. 5** | Mean Pulse rate before treatment | **64** |
| **Graph No. 6** | Mean Pulse rate during treatment | **65** |
| **Graph No. 7** | Mean change in pulse rate before and during treatment | **66** |
| **Graph No. 8** | Mean Frankl Behavior rating before treatment | **67** |
| **Graph No. 9** | Mean Frankl behavior rating scale after treatment | **69** |
| **Graph No. 10** | Mean change in Frankl behavior rating before and after treatment | **70** |

# LIST OF ANNEXURES


| *Annexure No.* | *Title* | *Page No.* |
|---|---|---|
| ***Annexure I*** | Ethical Committee Approval Form | **92** |
| ***Annexure II*** | Parent Consent Form- English | **93** |
| ***Annexure III*** | Parent Consent Form- Hindi | **94** |
| ***Annexure III*** | Statistician Form | **95** |
| ***Annexure IV*** | Antiplagiarism Report | **96** |

# INTRODUCTION

Local anaesthesia is a cornerstone in managing pain during dental procedures, particularly in paediatric dentistry, where the challenges of patient cooperation and comfort are paramount. Fear and anxiety associated with dental visits can significantly influence a child's willingness to seek care, thereby impacting their oral health outcomes. The anticipation of pain often exacerbates anxiety, an emotional response to anticipated threats, and fear, a reaction to perceived danger, in dental contexts. These emotions can lead to avoidance behaviors and distress, complicating effective dental care and exacerbating oral health issues.[1]

Children experiencing heightened dental anxiety often report exaggerated perceptions of pain, which prolong discomfort and instil negative memories of dental visits. This dual-edged nature of pain in dentistry—as both a motivator for seeking care and a deterrent due to fear—highlights the importance of managing emotional and physiological aspects of pain simultaneously. Addressing these challenges is crucial for fostering positive attitudes toward dental care in young patient.[2]

Pain is characterized as an unpleasant sensory and emotional experience that is linked to actual or potential tissue injury, or expressed in relation to such harm, as defined by the International Association for the Study of Pain. [3] Inadequate pain management in children can evoke negative responses and fears, posing significant barriers for dentists aiming to establish trust and positive attitudes in their paediatric patients. Effective pain management fosters trust, alleviates fear, and promotes a favourable dental experience.[4]

Local anaesthesia, central to pain management during paediatric dental procedures, is described by Malamed as a reversible loss of sensation in a specific body part, achieved by depressing excitation in nerve endings or inhibiting conduction in peripheral nerves. Local anaesthetics act by blocking the rapid sodium ion influx required for neurone impulse propagation, thereby preventing pain during procedures.[5] These agents not only minimise pain but also contribute to building trust

between the dentist and patient thereby, reducing fear and anxiety, and encouraging positive attitudes toward future dental visits. A wide array of local anaesthetic agents enables tailored care for individual needs.[6]

The delivery of local anesthesia has undergone significant advancements, revolutionizing its application in modern dentistry. The invention of the hypodermic syringe by Alexander Wood in 1853 marked a pivotal moment, enabling the precise delivery of injectable anesthesia and transforming pain management.[7] One such technique is precooling, also known as cryo-anaesthesia, which involves the application of localized cold to block nerve conduction of pain impulses. This approach stimulates myelinated A fibers, activating inhibitory pain pathways and raising the pain threshold. Research shows that cooling can effectively slow or eliminate pain signal transmission.[8] Common methods of precooling include the use of ice, either crushed or cubed, as well as refrigerant sprays such as Gebauer's Pain Ease and Pharma Ethyl. Despite its efficacy, precooling has a short duration of action, requiring an application time of 2-5 minutes to achieve its desired effect.[9]

Another innovative approach is iontophoresis, which enhances the transport of topically applied drugs by using mild electric currents. This technique increases the permeability of charged drugs through the skin, facilitating deeper penetration of anesthetic agents. By eliminating the need for a needle, iontophoresis offers a painless and effective alternative for pain management.[10]

Similarly, Transcutaneous Electric Nerve Stimulation (TENS) devices represent a syringe-free method of managing pain. These devices deliver electrical currents to stimulate nerves, making them particularly useful for children. The TENS system consists of an electric pulse generator, lead wires, and electrodes that can be placed intra-orally or extra-orally. It has been successfully employed in various procedures, including cavity preparation, pulpotomy, and extractions, to provide analgesia and reduce anxiety. Studies have demonstrated its effectiveness as an adjunct to conventional anesthetics, especially in minimizing pain during extractions and restorative procedures.[11]

## *INTRODUCTION*

Computer-Controlled Local Anesthetic Delivery Systems (CCLAD) represent a sophisticated advancement designed to facilitate the administration of anesthesia with minimal discomfort. These systems administer small amounts of anesthetic solution at slow, controlled speeds to minimize discomfort. Indicated for both pediatric and adult patients, CCLAD systems such as Compudent, Comfort Control Syringe®, and Single Tooth Anesthesia™ (STA) are equipped to provide tailored anesthetic delivery rates. For instance, the Compudent/Wand device, initially known as Wand, has undergone several iterations, including Wand Plus and CompuDent. This system comprises a base unit, handpiece, and foot pedal. It channels the anesthetic solution through micropore tubing, regulated by a computer-controlled unit. The flow rate of the injection is adjustable via the foot pedal, allowing for precise and painless administration.[12]

The Comfort Control Syringe® is an advanced version of the CCLAD system, featuring an electronic, pre-programmed delivery mechanism that enhances operator control for a more comfortable injection experience. The system starts the injection at a very slow rate to minimize the pain commonly caused by rapid delivery, gradually increasing the speed after 10 seconds to a pre-set rate based on the selected technique.[13] It offers five preset injection rates tailored for specific procedures: infiltration (0.007 ml/sec), regional block (0.02 ml/sec), palatal (0.008 ml/sec), intraligamentary (0.007 ml/sec), and intraosseous (0.02 ml/sec) injections.

The Single Tooth Anesthesia (STA) system incorporates vibration technology to reduce pain perception during injection, as well as pressure-sensing technology to monitor the pressure of the solution being administered. The STA system includes a foot pedal, cartridge holder, and tubing, enabling the operator to adjust the injection rate as needed.[12] Similar devices, such as the Quick Sleeper® and Sleeper One®, offer ergonomic designs aimed at minimizing discomfort during tissue penetration. The Quick Sleeper features a handpiece with a grip, a foot pedal, and a control unit, as well as a resistance analysis system that displays the amount of anesthetic solution used directly on the handpiece. The newest Quick Sleeper S4 model is 40% lighter and 19% smaller in diameter than its predecessors.[14] Likewise, the Sleeper One® device includes a pen grip handpiece, control unit,

foot pedal, and resistance analysis system, along with a recapping system to prevent accidental needle injuries. Its needles are designed to easily and painlessly penetrate various types of tissue.[11]

Another effective non-pharmacological pain-relief technique involves vibrotactile devices and vibratory stimulation during local anesthetic injections.[1] This concept is based on the gate control theory, proposed by Melzack and Wall in 1965, which posits that applying non-noxious stimuli, such as vibration, reduces pain sensitivity by stimulating larger-diameter nerve fibers.[15] Devices such as VibraJect and DentalVibe utilize this principle to mask pain. VibraJect (Miltex Inc., York, PA) is a compact device designed to reduce pain during local anaesthetic injections by using vibrations. This battery-powered device features an attachment that easily connects to a standard dental syringe. It generates high-frequency vibrations applied to the needle, helping to block pain sensations during the injection of the anaesthetic.[16] The DentalVibe (BING Innovations LLC, USA) is a portable, cordless injection system that utilizes a U-shaped vibrating tip connected to a microprocessor-controlled Vibra-Pulse motor. This device delivers pulsed, percussive vibrations with increased amplitude, which gently taps the mucosa in a rhythmic, variable pattern. This continuous stimulation of the α-β nerve fibers effectively masks pain sensations. The vibrating tip is placed on the injection site, allowing the dental needle to be inserted within the vibration zone. Additionally, the device illuminates the injection area and features an attachment to assist with retracting the lip or cheek.[16]

The Accupal (Hot Springs, AR, USA) is another cordless, battery-operated device designed specifically for inferior alveolar blocks and palatal injections. It combines both vibration and pressure to precondition the alveolar or palatal mucosa. By applying vibration and pressure around the injection site (360° around the needle penetration), the device activates the pain gate mechanism, which effectively blocks pain. The device includes a slotted head that attaches to the motor, and when placed with moderate pressure on the injection site, it vibrates and illuminates the area. The

needle is then inserted through the head, enabling the anesthetic solution to be delivered painlessly to the patient.

DentalVibe (BING Innovations LLC, USA) is a portable, cordless injection system featuring a U-shaped vibrating tip connected to a microprocessor-controlled Vibra-Pulse motor. The device delivers a pulsed, percussive vibration with increased amplitude, gently tapping the mucosa in a rhythmic and variable pattern. This action continuously stimulates the α-β nerve fibres, effectively masking pain sensations. The vibrating tip is applied to the injection site, and the dental needle can be inserted within the vibration zone. Additionally, the device illuminates the injection area and includes an attachment to help retract the lip or cheek.[16] The Accupal (Hot Springs, AR, USA) is a cordless, battery-operated device designed for inferior alveolar blocks and palatal injections. It combines vibration and pressure to precondition the alveolar or palatal mucosa. By applying both pressure and vibration around the injection site (360° around the needle penetration), the device activates the pain gate mechanism, effectively blocking pain sensations. The device features a slotted head that attaches to a motor. The head is placed on the injection site with moderate pressure, causing it to vibrate and illuminate the area. The needle is then inserted through the head, allowing the anaesthetic solution to be delivered painlessly to the patient.[16]

Jet injector technology has been utilized for several years, primarily in intramuscular injections, and operates by using mechanical energy to create sufficient pressure to propel a liquid medication through a small orifice. This results in a fine jet of fluid that can penetrate soft tissue and reach the subcutaneous layer without the need for a needle. The advantages of jet injectors include ease of use, minimal to no pain, reduced tissue trauma, faster drug absorption, and a lower risk of infection at the injection site. However, there is limited controlled research on their overall effectiveness, with much of the available evidence being anecdotal. In dental applications, jet injectors have shown limited efficacy, particularly for pulpal anesthesia, as they can only administer small volumes of anesthetic sufficient for soft tissue anesthesia.[17] They are more commonly used in pediatric patients due to their lower bone density. In oral surgery, jet injectors are typically used for vasoconstriction

or postoperative pain management. They also have other applications, such as removing fracture arch bars or ligature wires, applying orthodontic bands, and performing small punch biopsies. An example of such a device is the Syrijet Mark II jet injector (Keystone Industries, Cherry Hill, NJ, USA), which is commonly used by pediatric dentists. This device uses standard 1.8-ml cartridges of local anesthetic solution, allowing for the delivery of varying volumes between 0 and 0.2 ml. The Syrijet Mark II operates at a nozzle pressure of 2000 pounds per square inch (psi) and delivers anesthetic to a penetration depth of up to 1 cm, comparable to traditional needle injections, with a maximum volume of 0.2 ml per injection.[18] Another example is the Med-Jet (Medical International Technologies, Montreal, QC, Canada), a needle-free injection system that uses compressed air to deliver injections. The device is placed against the mucosa, and upon triggering, the solution is forced through the mucosa to induce anesthesia. It is capable of delivering injections intradermally, subcutaneously, or intramuscularly, with volumes ranging from 0.01 to 1 cc at a pressure of 2000 psi, and the penetration depth can be adjusted mechanically. This system is pain-free and is particularly effective for nasopalatine and greater palatine injections, though it is less effective for regional or pulpal blocks. It is especially successful in pediatric patients and has additional applications in mass vaccination, psychiatry, dermatology, and mesotherapy. However, drawbacks of the device include the potential for hematomas at the injection site and its high cost.[16]

Safety Dental Syringes designed to minimise accidental needle-stick injuries; these syringes incorporate locking mechanisms to ensure safety after use. Examples include ultra-safe syringe models and Rev Vac safety syringes.[19] Intraosseous Anaesthesia technique delivers anaesthetic solutions directly into cancellous bone, overcoming challenges associated with infiltration anaesthesia in dense mandibular regions. Systems like Stabident®, X Tip®, and Intraflow® provide effective intraosseous anaesthesia, with features such as pilot drills and hollow tubes for precise delivery.[20] Laser Analgesia **a**lthough not a complete substitute for anaesthesia, lasers disrupt impulse conduction temporarily, enabling soft tissue procedures like frenectomies without

injections. By altering the sodium-potassium pump, lasers provide a minimally invasive alternative for pain management in selected cases.[21]

Among the latest innovations, the **Starpen device (**Guilin Woodpecker Medical Instrument Co., Ltd.) represents a significant advancement in painless anaesthesia delivery. It is an electronic dental anaesthesia (EDA) system, combining artificial intelligence algorithms with pressure feedback technology, which offers precise control over injection speed and pressure, enhancing patient comfort. The device offers three different adjustable speeds—high, low, and hybrid—with two aspiration modes—manual and auto, resulting in a more pleasant experience for the patient. Despite its potential, there is limited literature comparing Starpen with other devices like Vibraject, particularly in paediatric settings. This study aims to evaluate behavior, anxiety, pulse rate, and pain perception using Starpen and Vibraject in children, contributing valuable insights into paediatric dental anaesthesia management.

# AIMS AND OBJECTIVES

## AIM

To compare and evaluate Behavior, Anxiety, Pulse rate and Pain perception using 2 different local anaesthesia delivery systems – Star Pen & Vibraject in children.

## OBJECTIVES

1. To evaluate pain perception in children using Star Pen and Vibraject.
2. To evaluate anxiety in children using Star Pen and Vibraject.
3. To evaluate pulse rate in children using Star Pen, and Vibraject.
4. To evaluate Starpen and Vibraject as behavior management tool.

# REVIEW OF LITERATURE

1. Ahmad N, Jindal MK, Agrawal N & Varshney P. (2024) [22] evaluated the perception of pain and fear during local anesthetic (LA) administration in pediatric patients aged 6 to 12 years, comparing the camouflaged syringe (CS), vibration-assisted syringe (VA), and conventional syringe, as well as the combined use of CS and VA (VACS). A total of 85 subjects were randomly assigned to three groups. Physiological parameters and psychometric scale readings were recorded before and after the injection. The primary objective was to assess the differences in fear and pain levels associated with the CS and VA systems compared to conventional syringes using psychometric and physiological scales. The secondary objective was to determine patient preference for the various injection techniques. The findings indicated that pain and fear control were superior in the CS group using the camouflaged syringe, in the VA group using the vibration-assisted syringe, and in the VACS group using the vibration-assisted syringe. Patient preferences aligned with these results, with 64% of the CS group preferring the camouflaged syringe, 60% of the VA group preferring the vibration-assisted syringe, and 52% of the VACS group favoring the camouflaged syringe. In the VA group, post-injection heart rate (HR), diastolic blood pressure (DBP), Visual Analogue Scale (VAS), and SEM (Sound, Eye, and Motor) scores showed statistically significant differences in mean values, favoring the vibration-assisted syringe over the conventional syringe. This indicated that the vibration-assisted syringe was more effective at reducing fear and pain in children receiving inferior alveolar nerve blocks (IANBs). In the VACS group, post-injection VAS and SEM scores also revealed statistically significant differences between the vibration-assisted syringe and the camouflaged syringe, with the vibration-assisted syringe demonstrating better performance in minimizing fear and pain during IANB procedures. The authors concluded that both the vibration-assisted syringe (VibraJect) and the camouflaged syringe are superior to conventional syringes in terms of reducing pain and fear in children aged 6–12 years undergoing inferior alveolar nerve block procedures. Furthermore, the

vibration-assisted syringe exhibited better overall control of pain and fear compared to the other two techniques. Preference for the camouflaged and vibration-assisted syringes was significantly higher than for the conventional syringe, further supporting their use in pediatric dental procedures.

2. Anil Ö & Keskin G (2024) [23] investigated the effects of infiltrative anesthesia delivered using two different techniques on pain and anxiety in children, using psychometric, physiological, and biochemical assessments. Sixty children aged between 7 and 11 years, participated in the study. They were divided into two groups: the control group, which received traditional injections, and the study group, which underwent anesthesia using computer-controlled local analgesic delivery (CCLAD). Various parameters were recorded, including physiological measures such as pulse and oxygen saturation (SpO2), biochemical markers like salivary cortisol levels, and psychometric scale scores. The scales used were the Visual Analogue Scale (VAS), Wong-Baker Faces Pain Rating Scale (WBS), Modified Child Dental Anxiety Scale (MCDAS), and Face, Legs, Activity, Cry, Consolability Behavioral Pain Assessment Scale (FLACC). The results revealed significant differences in pulse rates between the two groups at various times of measurement. In the control group, pulse rates increased over time, with post-anesthesia (P3) values being higher than pre-anesthesia (P1), and P1 values lower than those recorded during anesthesia (P2) and post-anesthesia (P3). However, no significant difference was observed between P2 and P3 in this group. In contrast, the study group exhibited higher P2 values compared to P1, but no significant differences were noted between P1 and P3 or between P2 and P3. Despite these changes in pulse, no significant differences were observed in SpO2 values at any measurement point in either group. This lack of variation in SpO2 may be attributed to the delay in reflecting changes on the pulse oximeter compared to pulse rate measurements. The psychometric scale scores also demonstrated notable differences. While initial VAS scores (VAS 1) were similar between the groups, post-anesthesia VAS scores (VAS 2) were significantly higher in the control group compared to the study group, indicating that CCLAD was associated with lower pain levels. For MCDAS, initial scores (MCDAS 1) were

lower in the control group than in the study group, but post-anesthesia scores (MCDAS 2) were lower in the study group than in the control group, reflecting reduced anxiety in patients who received CCLAD. Similarly, FLACC scores showed that initial values (FLACC 1) were lower in the control group than in the study group, while post-anesthesia values (FLACC 2) were lower in the study group, suggesting better pain control with CCLAD. Significant changes in FLACC and MCDAS scores were observed between the first and last measurements within both groups, reflecting varying levels of pain and anxiety over time. In conclusion, the study found an increase in pulse values following anesthesia in both groups, while SpO2 values remained consistent, likely due to delays in measurement updates on the pulse oximeter. The findings highlighted that the CCLAD technique resulted in lower post-anesthesia pain and anxiety levels compared to traditional injections. These differences in pain and anxiety control may be influenced by factors such as the age and cooperation of the pediatric patients, the technical sensitivity of the anesthesia method, or the skill of the practitioner. Overall, the study suggested that CCLAD offers significant advantages in managing pain and anxiety during infiltrative anesthesia in children.

3. Patel M et al (2024) [24] evaluated pain perception, anxiety reduction, and patient preference between the computer-controlled Starpen device and the conventional aspirating cartridge for administering local anesthesia (LA) during inferior alveolar nerve block. Patients were randomly divided into two groups, with one group receiving LA injections via the Starpen device and the other through the Septodont syringe in the first week. Following a one-week washout period, a crossover was conducted, and the alternate method of LA administration was used in the second week. Pain scores were objectively assessed by the observer using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale during LA administration and tooth extraction. Additionally, patients self-reported pain scores using the Visual Analogue Scale (VAS) at three distinct phases: (a) mucosa perforation, (b) needle insertion, and (c) solution injection. The study also evaluated the impact of pain perception on vital parameters and recorded the patients' preference between the two techniques. Intragroup comparisons within

the Septodont syringe group revealed a statistically significant variation in pain scores across the different stages of LA administration and extraction. In contrast, no statistically significant differences in pain scores were observed within the Starpen group. When intergroup comparisons were made, significant differences in pain scores were noted at all stages of LA administration and extraction, with the Starpen device showing lower pain scores. Furthermore, the study identified a statistically significant difference ($P \leq 0.001$) in pain perception between the two groups during both the administration of LA and the extraction process. The authors concluded that the Starpen device offers the potential to provide a positive and stress-free dental experience for children requiring dental care. The device's adjustable speed for anesthetic administration and its three unique aspiration modes make it a promising alternative for delivering dental anesthesia to children, effectively reducing pain and anxiety.

4. Albar NH et al (2024) [25] compared pain perception levels between a needle-free injection system (INJEX) and the traditional syringe needle method in pediatric patients undergoing the restoration of young permanent teeth. Sixty participants requiring indirect pulp capping in young permanent first molars were included. The results revealed no significant differences in observed pulse rates before and one minute after local anesthesia (LA) administration between the two groups. While pulse rates at other time intervals showed no significant variations, a statistically significant difference was noted during anesthesia administration, with higher pulse rates observed in the traditional syringe group. Analysis of the Face, Behavior, Restlessness, and Sleep (FBRS) scores indicated no significant differences across all three time periods—before, during, and after anesthesia. However, the FLACC scale revealed a statistically significant difference during LA administration, with lower scores reported in the needle-free injection group, indicating reduced behavioral pain. Wong-Baker Faces Pain Scale (WBS) scores demonstrated statistically significant differences between the groups at multiple time points: before the procedure, immediately after injection, during the treatment, and at the end of the treatment. The traditional syringe group consistently recorded higher WBS scores. Intra-group analysis of pulse rates, FBRS, and WBS further highlighted significant differences across

time periods for both groups, except for the WBS scores when comparing immediately post-injection to during treatment, where no significant difference was noted. The authors concluded that the INJEX needle-free injection system was more effective than the traditional dental needle method for achieving anesthesia in restoring young permanent molars. Pain perception levels were notably lower with INJEX, and patient cooperation during procedures was higher. The needle-free jet injection system thus offers a promising alternative for administering dental anesthesia, enhancing patient comfort, and reducing the anxiety associated with traditional injections.

5. N S, Sharma A, Siddaiah MK & Subramaniam P (2024) [26] compared the pain perception in 4–6-year-old children following intraoral dental injections using 26-gauge and 31-gauge needles. The gauge for the first visit's local anesthesia administration was randomly selected using a lottery method. Children's reactions to pain were evaluated using a Modified Behavioral Pain Scale, and pain perception was assessed immediately after the injection using the Faces Pain Rating Scale. During a subsequent visit, the other needle gauge was used, and the same evaluations were performed. At the third appointment, children were presented with both syringes and asked to choose their preferred one. The results indicated that when local anesthesia was administered using the 31-gauge needle, pain perception was similar between the two groups. However, children in the group receiving the 26-gauge needle (Group II) exhibited significantly higher arm and leg movements ($P = 0.001$), indicating greater discomfort. Notably, the difference in pain perception was significant in Group I alone ($P < 0.001$). The authors concluded that, regardless of age, anesthesia with a 31-gauge needle resulted in significantly lower pain perception compared to the 26-gauge needle. This suggests that using finer needles may enhance the comfort of pediatric patients during dental procedures, making it a preferable choice for local anesthesia administration.
6. Rajan RE et al (2024) [27] evaluated whether camouflaged syringes compared to conventional syringes have a favorable impact on the behavior and anxiety levels of the children according to variations in pulse rates, Face, Legs, Activity, Cry, Consolability (FLACC) behavior pain

scale and facial image scale (FIS). The study included 60 children divided into two age-groups (3–6 years and 6–9 years). It was also registered in Clinical Trials Registry, India (CTRI) as a prospective study with CTRI number CTRI/2023/08/056189. Conventional syringes were used in the first appointment, and camouflaged syringes in the second, employing a split-mouth design. Prior to block administration, a topical anesthetic gel was applied. Pulse rates were noted before and during the block administrations using a pulse oximeter. Behavior was evaluated by the FLACC scale before and during the administration of local anesthesia (LA). After the injection, children were expressed their anxiety during the block administration using FIS. Pulse oximeter showed a small decrease in readings while the camouflaged syringe was used in both groups. This indicated that child had lower anxiety levels while using camouflaged syringes which was highly statistically significant. When camouflaged syringes were used, the mean FLACC scores in both groups dropped, indicating improved behavior. An increased percentage of children stated lower anxiety levels by indicating happy face in the FIS after the procedure in both the groups while using camouflaged syringes. Authors thereby concluded that innovative methods, such as camouflaged syringes, as a distraction technique to manage anxiety in children and thereby inducing a positive dental experience.

7. Naji DK & Jafar ZJ (2024) [28] assessed the patient cooperation and behavior after receiving local anesthesia injection and to compare patients' acceptance and preference of needleless NumBee anesthetic delivery device to conventional dental syringe. 30 non-fearful 6-8-year-olds who had never been to the dentist were selected for the study using a split-mouth design. They underwent a simple class I restoration on both mandibular permanent first molar teeth in two separated dental visits. The Frankl behavior rating scale was used to assess patient behavior following injection. Patients expressed their preference and acceptance of the used syringes by answering a questionnaire. Results showed that on comparing both modalities of injection of Frankl behavior rating scale by using the marginal homogeneity test, Frankl behavior rating scale score 4 was the most prevalent score among the participants after receiving the injection using either method. Frankl behavior rating scale score 3 was reported in both methods but was

more frequent after inferior alveolar nerve block injection. Patients showed a score of less cooperative status (score 2) on Frankl behavior rating scale for both methods but it was higher in NumBee injection. the McNemar's test showed that the NumBee injection induced less fear in participants, a less unpleasant state after injection with a lesser number of participants who experienced a stinging sensation in comparison with inferior alveolar nerve block method, however; with statistically non-significant difference. This could be because of a lesser degree of the profound anesthesia anticipated from NumBee, as anesthesia is infused into the epithelium and connective tissue that lies between the gingival sulcus's base and the PDL according to the manufacturer. This means, as compared to the conventional needle injection, that less local anesthetic is defused to the marrow spaces of the bone around the teeth, giving less chance to provide deep sensation of tooth numbness. This gave rise to lesser negative behavior in Frankl behavior score towards NumBee injection compared to the inferior alveolar nerve block. It was therefore concluded that patients in this study disclosed their acceptance and preference equally for both methods; however, less fear was induced in patient who were injected by NumBee.

8. Singh K, Jhingan P, Mathur S, Malik M & Kashyap K (2024) [29]compared and evaluated the efficacy of transcutaneous electrical nerve stimulation (TENS) and a vibrational precooling system in reducing pain and anxiety during the administration of local anesthesia in children aged 6–12 years old. A total of 60 children aged 6–12 years old participated in this randomized controlled trial and were randomly allocated to three groups: the conventional method group, the vibrational precooling system group, and the TENS group. Results revealed a statistically significant reduction in pain was observed with the usage of the vibration system and TENS, as measured by the FLACC scale, compared to the conventional method group. Similarly, statistically significant differences in SEM scores were noted between the vibrational precooling system group and the conventional method group, as well as between the TENS group and the conventional method group, with the highest scores observed in the conventional method group. The children reported the highest comfort levels with the usage of the vibration

system, as indicated by the self-administered VAS. However, no statistically significant difference was observed within any group. Authors concluded that the new vibrational precooling system as well as TENS can be effectively used to alleviate the pain experienced during the administration of local anesthesia.

9. Mohamed MA, Abuelniel GM & Yousry YM (2023) [30] compared the effectiveness of a vibration-assisted syringe versus a conventional syringe in managing pain and anxiety perception during local anesthetic injection in children. The study aimed to evaluate whether the vibration-assisted syringe could provide a more comfortable and less stressful experience for pediatric patients undergoing local anesthesia. Participants included children who required dental treatment with local anesthetic injections. They were randomly assigned to two groups: one receiving anesthesia with the vibration-assisted syringe and the other with the conventional syringe. Pain perception was assessed using the Wong-Baker Faces Pain Scale (WBS), while anxiety levels were measured using an appropriate psychometric scale. The results indicated that children who received local anesthesia with the vibration-assisted syringe reported significantly lower pain and anxiety scores compared to those who were treated with the conventional syringe. The vibration-assisted syringe demonstrated superior performance in minimizing discomfort and reducing anxiety associated with needle insertion and anesthetic administration. The authors concluded that the vibration-assisted syringe is an effective tool for managing pain and anxiety during local anesthesia in children. Its ability to distract and provide counter-stimulatory effects makes it a promising alternative to conventional methods, enhancing the overall dental experience for pediatric patients.

10. Vitale MC, Gallo S, Pascadopoli M, Alcozer R, Ciuffreda C & Scribante A (2023) [31] evaluated and compared patient discomfort during local anesthesia administration using a traditional syringe versus the CCLAD system SleeperOne®. A total of 30 patients were randomly assigned to either the traditional anesthesia group or the SleeperOne® group. Discomfort was assessed using a Visual Analogue Scale (VAS) from 0 to 10, focusing on pain, size sensation, bitterness, and vomit perception. Results showed that patients in the SleeperOne® group reported

statistically lower mean pain scores compared to those receiving traditional injections. The technique significantly influenced pain, with the SleeperOne® device proving to be more comfortable. However, there were no statistically significant differences between the two groups concerning size sensation, bitterness, or the urge to vomit. Further analysis revealed that pain perception was influenced by the type of dentition, with higher scores observed in patients with primary (deciduous) teeth compared to those with permanent teeth. Additionally, pain perception decreased with age, suggesting that older patients may have a greater tolerance for discomfort. Notably, bitterness perception was higher for primary first molars. In conclusion, the SleeperOne® device effectively reduces pain associated with anesthetic injections, especially in children. While it did not significantly affect perceptions of size, bitterness, or nausea, its ability to lower pain levels highlights its value as a more comfortable alternative to traditional syringes in dental practice.

11. Bagher SM, Felemban OM, Alsabbagh GA & Aljuaid NA (2023) [32] evaluated the impact of using a camouflaged dental syringe on anxiety and behavioral pain in children, compared to the traditional dental syringe, during local anesthesia (LA) administration. This randomized clinical trial included cooperative and healthy pediatric patients aged 6 to 10 years, who were scheduled for non-urgent dental treatment requiring buccal infiltration anesthesia (BIA) in the maxillary arch. Participants were randomly assigned to either the test group, where BIA was administered using the camouflaged dental syringe, or the control group, where the traditional dental syringe was used. The children's anxiety levels were measured using Venham's Anxiety Rating Scale (VARS), while their behavioral pain was assessed using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale. Results showed no statistically significant differences in heart rate (HR) between the two groups at baseline, during needle insertion, or one minute after the administration of LA. On the VARS, most subjects in both groups scored zero, indicating they were relaxed and quiet during the LA procedure. Although the VARS scores in the test group were slightly lower compared to the control group, this difference did not reach statistical significance. In contrast, the FLACC scores were significantly lower in the test group compared

to the control group, indicating reduced behavioral pain in children who received LA with the camouflaged dental syringe. The decrease in FLACC scores suggested improved behavior and a more positive response to the camouflaged syringe. The study concluded that camouflaged dental syringes could enhance the overall dental experience for pediatric patients. They present a viable alternative to traditional syringes for administering local anesthesia, potentially reducing behavioral pain and improving cooperation in children during dental procedures.

12. Yousry YM, Mohamed MA, Abuelniel GM (2023) [33] evaluated the effectiveness of vibration-assisted syringes compared to conventional syringes regarding pain and anxiety perception during dental local anesthetic injections in children. A total of 46 children aged 4 to 6 years were randomly assigned to two equal groups. Group I received intraoral injections using vibration-assisted syringes, while Group II received injections with conventional syringes. Children's reactions to pain from the needle prick and the local anesthetic injection were measured using a Visual Analogue Scale (VAS), while anxiety levels were assessed using a visual facial anxiety scale. The results indicated that Group II (conventional syringe) had higher pain scores than Group I, but the difference was not statistically significant ($p = 0.484$). Similarly, although Group II showed higher anxiety scores compared to Group I, this difference was also not statistically significant ($p = 0.551$). No significant associations were found between gender and pain or anxiety in either group ($p > 0.05$). Additionally, a weak negative correlation between pain and age was noted, which was statistically significant in Group II. The authors concluded that the use of a vibration-assisted syringe did not lead to a significant reduction in perceived dental pain or expressed anxiety in children when compared to the conventional syringe. This suggests that while vibration-assisted syringes may offer benefits, they may not be significantly more effective than traditional methods.

13. Albouni MA, Kouchaji C, Al-Akkad M, Voborna I & Mounajjed R (2022) [1] conducted a study comparing the effectiveness of conventional syringe injections and Vibraject-assisted injections (VAI) in reducing pain during various intraoral local anesthesia procedures for children aged 6 to 9 years. A total of 75 children were selected for the study, and each child received both types

of anesthetic injections: the conventional syringe injection and the Vibraject-assisted injection. These injections were administered over the course of two separate dental visits, spaced two weeks apart, to allow for an unbiased comparison. The results of the study indicated that children who were given local anesthesia through the Vibraject method experienced significantly lower levels of pain during needle insertion, as evidenced by their lower scores on both the Visual Analog Scale (VAS) and the Face, Legs, Activity, Cry, Consolability (FLACC) scale—two widely used tools for assessing pain in pediatric patients. In contrast, children who received anesthesia via the conventional syringe reported higher pain levels. Based on these findings, the authors concluded that the Vibraject method is more effective in minimizing the pain associated with local anesthetic injections compared to the traditional syringe technique. This is particularly important in pediatric dental procedures, where patient comfort is critical for achieving a successful outcome. Furthermore, the study suggested that the use of VAI not only reduces discomfort but also contributes to greater ease in administering the injection, improved patient cooperation, and better compliance during dental care sessions, which are often challenging with young children.

14. Kohli N, Hugar SM, Patil VH, Saxena N, Kadam KS & Karmarkar S (2022) [34] evaluated and compare anxiety levels and pain perception using conventional, insulin, and deception syringes during the administration of local anesthesia in children. : Forty-five children aged 6–12 were selected using a standard sample size formula and equally divided into three groups. Local anesthesia was administered using a conventional syringe to Group A participants and an insulin syringe for Group B participants. Group C participants were administered local anesthesia using a deception syringe by showing the patient disposable obturation tips, and eventually a conventional syringe was used for administration of local anesthesia after hiding them from the patient. Anxiety levels were assessed using Venham's Picture Scale and pulse rate at baseline and after administration of local anesthesia. The Wong-Baker Faces Pain Rating Scale was used to assess pain perception after the administration of local anesthesia. A highly statistically significant difference was found in the insulin syringe group, indicating that it was

the most efficient in reducing anxiety. In contrast, an increase in anxiety levels was observed in the conventional syringe group. However, when comparing the insulin syringe group with the deception syringe group, a non-statistically significant difference was observed, indicating the efficacy of both modalities in reducing anxiety among children during local anesthesia administration. The insulin and deception syringe groups also showed a marginal increase in the pulse rate, but the difference was not statistically significant. In accordance with these findings, when intergroup comparison was carried out using Tukey's multiple posthoc procedures, a highly statistically significant difference in mean pain perception scores was observed between the conventional and insulin syringe groups. This could be attributed to the fact that the insulin syringe has a smaller size and brighter color, which makes it appear like a toy. Plastic obturation tips used in the form of a deception syringe also removed fear-provoking stimuli. However, insulin syringes cannot be used for nerve blocks because of the shorter length of the needle. In contrast, a deception syringe can be easily used before administering any form of injection. It was therefore concluded by the authors that the use of insulin and deception syringes for administration of anesthesia was demonstrated to be effective in alleviating anxiety in children and is therefore recommended as an alternative to conventional syringes.

15. Beegum N, Nandan N, Raj SN &Vishwanathan S (2022) [35] evaluated dental anxiety in children aged 6 to 8 years at the time of administration of local anesthesia, during intracanal irrigation and after treatment with the use of conventional and camouflaged syringe. Dental anxiety was assessed using two parameters- The Pulse Rate and Facial Image Scale (FIS) score. Pulse rate was measured using pulse oximeter and FIS score was recorded using Facial Image Scale (FIS). Both the parameters were documented in experimental and control groups at the time of administration of local anesthesia, during intracanal irrigation and after treatment. The results reported that at the time of administration of LA the pulse rate was maximum. This could be because the sight of needle for the first-time induced anxiety in children and later a constant decrease in pulse rate was observed with progress in time. Thus, it can be inferred that pulse rate decreases with progress in treatment, with a minimum value noted at the end of the

treatment. Results also showed that the age group of 6 to 8 years preferred camouflaged syringe because they are more easily distracted and the toy like alligator appearance of the camouflaged syringe carried away the fear inducing stimuli of conventional syringe. The results of this current study strongly recommended the use of camouflaged syringes to reduce dental anxiety in children. It was therefore concluded that the camouflaged syringes were best to deliver local anesthesia and reduce pain and fear effectively.

16. Khalil MNH, Abbas AN & Abd Allah AE (2022) [36] compared the efficacy of two comfort systems—VibraJect (VJ) and DentalVibe (DV)—along with topical anesthesia (TA) using 20% benzocaine, in alleviating pain associated with local injections in children. A total of 150 children attending a pediatric dental clinic were selected and equally divided into three groups of 50 each. The groups received local anesthetic injections as follows: one group with the VJ system, another with the DV system, and the third with topical anesthesia. Pain levels during injection were evaluated subjectively using the Wong-Baker FACES pain rating scale, where children selected a face that best represented their feelings. Additionally, pain was assessed objectively using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale, which involved observing the children's behavior during anesthesia administration. The findings revealed that both the VJ and DV systems effectively reduced pain associated with local anesthetic injections delivered via infiltration and nerve block. Children in the VJ and DV groups reported significantly lower pain scores compared to those in the control group (TA). Moreover, the study indicated that the use of VJ and DV systems reduced pain during local anesthesia injections without causing increased anxiety compared to conventional methods. Overall, the study supports the effectiveness of vibration-assisted technologies in enhancing patient comfort during pediatric dental procedures, highlighting their potential as valuable tools in managing pain during local anesthesia administration.

17. Midha V et al (2021) [2] evaluated and compared the efficacy of various adjunctive aids for local anesthesia (LA) administration in reducing pain and anxiety in pediatric patients aged 6 to 8 years. A total of 90 child dental patients were randomly divided into six groups: control, topical

gel, audio, audiovisual, transcutaneous electric nerve stimulation (TENS), and Vibraject. Physiological parameters, psychological parameters, and pain assessments were recorded throughout the study. Results indicated that the minimum pulse rates during and after LA administration were observed in the audiovisual (A/V) and TENS groups during the injection, suggesting lower physiological stress. Children in the audiovisual and TENS groups exhibited less anxiety and were more relaxed compared to other groups. Both the TENS and Vibraject groups demonstrated the greatest reduction in pain perception. The authors concluded that the A/V and TENS groups resulted in the least anxiety levels among participants, while TENS and Vibraject were most effective in minimizing pain. These findings suggest that these adjunctive aids may be valuable tools in enhancing comfort and reducing pain during local anesthesia administration in pediatric dentistry.

18. Patil SB et al (2021) [37] compared and evaluated the effectiveness of four pain relief methods-Transcutaneous Electrical Nerve Stimulation (TENS), 2% lignocaine gel, the eutectic mixture of lignocaine and prilocaine (EMLA), and a vibrating device—before local anesthesia (LA) injections in pediatric patients. The participants included 60 healthy children aged 6 to 12 years who required LA injections for dental procedures. They were randomly divided into four groups, with 15 patients in each group. Pain perception was measured using two established scales: Wong–Baker's Facial Pain Rating Scale (WBFPRS) and the Face, Legs, Activity, Cry, and Consolability Scale (FLACC). The data collected from these assessments were tabulated and subjected to statistical analysis. The results demonstrated that the TENS group had the lowest mean scores on both the WBFPRS and FLACC, indicating that this method was the most effective in alleviating pain during LA injections. The vibrating device followed next in terms of effectiveness, while EMLA gel and lignocaine gel provided less pain relief compared to the other methods. The authors concluded that the newly introduced TENS apparatus showed promising results, suggesting that it could be a safe and reliable technique for managing pain in pediatric dentistry. This indicates potential for TENS to enhance the comfort and overall

experience of young patients during dental treatments, making it a valuable addition to pain management strategies in pediatric settings.

19. Fernández-Castellano ER, Blanco-Antona LA, Vicente-Galindo P, Amor-Esteban V & Flores-Fraile J (2021) [38] conducted a study to compared the pain experienced by patients during local anesthetic (LA) injections across different areas and procedures, utilizing both the traditional syringe and the controlled flow technique provided by the Dentapen® system. This randomized, controlled, single-blind, and single-centre study included 178 voluntary adult participants aged 18 to 90 years. Patients rated the pain experienced during the injections using a 10-point Visual Analogue Scale (VAS). Additional parameters, including pain index, heart rate, blood pressure, and oxygen saturation, were recorded both before and after the administration of anesthesia. The results highlighted significant differences in pain levels between the two delivery methods. The mean VAS score for injections administered with the conventional syringe was 2.63 ± 1.86, compared to 1.06 ± 1.28 with the Dentapen® system, demonstrating statistically significant differences (p-value < 0.01). When stratified by procedure type, significant differences (p-value < 0.01) were observed across most treatments, except for endodontics, where the differences were likely to be significant but not definitive. The data further revealed that patients reported notably lower pain levels in all areas where the Dentapen® syringe was used. This system also provided greater stability during administration. Conversely, conventional syringes were associated with a sharp increase in pain perception, with variations observed based on the injection site. Among all sites, patients experienced the least pain in the vestibular area with both systems, with significant differences noted compared to other injection localizations. The authors concluded that computerized controlled local anesthetic delivery (CCLAD) systems, such as the Dentapen®, offer a significant advantage by maintaining a consistent injection flow at a fixed pressure, regardless of variations in tissue resistance. This controlled flow ensures an ideal and steady delivery of the anesthetic solution, which is likely the most critical factor in minimizing pain and discomfort during injections. The

findings support the use of CCLAD systems as a superior alternative to traditional syringes for improving patient comfort and reducing pain during dental procedures.

20. AlHareky M et al (2021) [39] investigated the efficacy of a device combining cold and vibration, for needle-related procedural pain in children. A total of 51 children aged 5–12 years participated in this randomized controlled clinical trial. There were no statistically significant differences between the two groups regarding how parents perceived the last dental visit to be positive, children's comfort with dentist and anesthesia, or pain severity. Before injection, children in the test group expressed almost a similar pain to those in the control group on the VAS scale, and the evaluator assessed that they had a similar pain experience using the FLACC scale and SEM scale. After injection, children in the test group expressed a significantly lesser pain than those in the control group on the VAS scale. There was no difference between the two groups in parents' rating of child's tolerance of injection. results showed that the experimental device demonstrated a statistically significant effect on reducing self-reported procedural pain, observer-reported reaction to pain and anxiety, and parent-reported reaction to pain and anxiety during dental anesthesia related procedures. The authors therefore concluded that external cold and vibration application can significantly reduce the experienced pain during maxillary infiltration anesthesia in children.
21. Verma R, Khanduja R & Gupta S (2021) [40] evaluated the pain perception while administering bilateral mandibular local infiltration, in children undergoing dental procedures, by using comfort control injection and insulin syringe. Children between 5–9 years of age require local anesthesia on both sides of the arch for various dental procedures were included in the study. A total of 15 patients were selected and divided into two groups of 15 patients each as it was a split-mouth study. Group "A" patients were administered local anesthesia by a comfort control injection device and Group "B" by insulin syringes. The mandibular local infiltration was administered using a comfort control device on the left side and the insulin syringe on the opposite side of 0.5 mL at the first appointment and subsequent appointment respectively. Prior, during, and after the procedure, the heart rate and saturated oxygen rate were measured using a

pulse oximeter and FLACC and MCDAS were recorded. Results revealed a non-significant difference in the mean heart rate before and after local infiltration, but a significant difference was seen during local infiltration. There was no significant difference in SpO2 level found throughout the procedure in both groups. a significant difference was observed in the mean value of heart rate between comfort control and insulin syringe during local infiltration. This could be attributed to the fact that comfort control system showed better results because of its pen-like grasp of the handpiece that allows the operator to maintain a gentler and control manipulation of the needle. So minimal force is needed throughout the administration and a slow rate of anesthesia delivery dose appears to reliably reduce the pain-related disruptive behavior in young children. It was therefore concluded that the computerized control local anesthesia delivery systems seem to be the foremost effective procedures to deliver anesthetic agents without pain and anxiety.

22. Suohu T, Sharma S, Marwah N & Mishra P (2020) [41] evaluated the pain perception and patient comfort during local anesthesia (LA) delivery using the Buzzy system compared to a conventional syringe. Fifty children aged 5 to 10 years, requiring LA for dental treatments, were randomly divided into two groups. To assess pain perception, the Wong Baker Faces Pain Rating Scale (WBFPRS) was used for subjective evaluation, while the objective evaluation included measurements from a pulse oximeter and the Face, Legs, Activity, Cry, and Consolability (FLACC) scale. Statistical analysis of the results showed that the FLACC scores were significantly higher in the conventional syringe group compared to the Buzzy group. This indicates that children receiving LA with the Buzzy system experienced less discomfort and anxiety. The authors concluded that the Buzzy system, which employs external cold and vibration, effectively reduces pain and anxiety during LA delivery in pediatric patients. This suggests that incorporating the Buzzy system into dental practice can enhance the overall experience for young patients, making dental procedures less distressing.

23. Jalali F, Shojaeepour S & Shojaeepour R (2020) [42] compare the FLACC and SEM scales for children's pain perception and behavioral feedback during local anesthetic injection, which is

the strongest painful stimulus. This split -mouth study was conducted on 49 healthy children aged 3.5 to 9 years who needed dental treatment of bilateral primary molars under local anesthesia. The patients were randomly assigned to two groups. The level of anxiety was recorded at baseline and during local anesthetic injection according to the face-legs-activity-cry-consolability (FLACC) and the sound-eyes-motor (SEM) scales in the two groups. Then, the level of pain experienced by the child was determined according to the visual analog scale (VAS). Data were analyzed by SPSS version 20 using Mann -Whitney and Wilcoxon tests at 0.05 level of significance. Results showed that there was no statistically significant difference in pain score based on VAS after local anesthetic injection in the first and second sessions between the SEM (P=0.877) and FLACC (P=1.00) groups. This study showed that there was no difference between the SEM and FLACC scales regarding pain perception during local anesthetic injection in children, and some parameters of the two scales that were measured in the children's face area were behaviors that the children exhibited during local anesthetic injection.

24. Sathyaprasad S, Divyia J, Moorthy KSH, Nair RR & Prabhu S (2020) [43] assessed the effect of a modified behaviour management procedure applied as a novel technique on the level of pain perception in children receiving LA in a dental procedure. A randomised clinical trial was conducted among a study group of 65 children of frankel rating 2 and 3 are selected and a modified syringe pattern camouflaged with the child's favourite cartoon character is introduced during local anesthesia administration thereby desensitising and guiding the child to think different or see a new point of view to the previously fearful situation. The control group is subjected to injection using a normal syringe with no modification. This difference between the groups was found to be statistically significant. Only 15% of the children scored the maximum value of 6 which scored for maximum pain in the study group when compared with the control group where 32.50% children scored for the maximum score of 6, thus giving a statistically significant result in the intervention group. Results showed that adult reassurances is associated with increased child distress whereas distraction is associated with increased child coping.

Higher rate of fear was observed with methods such as reassurance rather than distraction. It was concluded that the behaviour scale showed a better management of children wherein the modified syringe pattern was used rather than where the normal pattern was used. The use of this technique would help us to overcome the major hurdle of fear in children during LA administration.

25. Tirupathi SP & Rajasekhar S (2020) [44] evaluated the effectiveness of vibration as a counter-stimulatory measure in reducing subjective pain during local anesthesia (LA) administration in children. A systematic review and meta-analysis included seven studies involving 376 children aged 5–17 years. The analysis compared the use of vibration as a counter-stimulatory method with no vibration, assessing its impact on pain perception and objective pain during LA administration. The primary outcome measured was the subjective pain reported by the child, while the secondary outcome was objective pain evaluated in each study. The pooled results demonstrated a significant difference favoring the use of vibration for reducing subjective pain. Lower pain scores were consistently reported when vibration was applied as a counter-stimulatory measure during LA administration. The authors concluded that intraoral vibration is an effective counter-stimulatory technique for reducing the pain perceived by children during intraoral local anesthesia administration, making it a valuable addition to pain management strategies in pediatric dentistry.
26. Veneva E, Cholakova R, Raycheva R & Belcheva A (2019) [45] conducted a study to determine the efficacy of the DentalVibe (DV) device in reducing pain and anxiety associated with local anesthesia (LA) in pediatric patients aged 8 to 12 years who required buccal infiltration for the extraction of two bilateral primary maxillary molars. Following an initial measurement of dental fear, eligible patients underwent two single-visit treatments where the DV device was allocated for either the first or second LA, based on a computer-generated randomization sequence. The outcome measures included several assessments: self-reported pain levels during LA using the Visual Analogue Scale (VAS), self-reported anxiety levels assessed with the Facial Image Scale, pain-related behavior measured by the Faces, Legs, Activity, Cry,

Consolability (FLACC) Scale, heart rate monitoring, and patient preference regarding the LA technique. The authors concluded that evaluating both subjective and objective measures of pain sensation and anxiety during these dental procedures could provide valuable insights into the clinical effectiveness of the DV-assisted infiltration method. By determining whether pain-free LA can be consistently achieved with the use of the DentalVibe device, the study aims to enhance the understanding of its potential benefits in pediatric dentistry, ultimately improving patient comfort and reducing anxiety associated with dental treatments.

27. Hegde KM et al (2019) [3] compared the effectiveness of a child-friendly device, which combines both vibration and distraction techniques, with the conventional injection method for administering local anesthesia, in terms of reducing pain, anxiety, and managing the behavior of pediatric patients aged 6–11 years. The study involved 30 children who required a bilateral inferior alveolar nerve block. These children were divided into two age groups: Group 1, consisting of children aged 6–8 years, and Group 2, made up of children aged 9–11 years. Each child underwent two separate sessions in which local anesthesia was administered using both the conventional injection method and the child-friendly device. Anxiety levels were measured by monitoring the pulse rate of the children before and during the administration of the local anesthetic. The pain response was further evaluated using the FLACC scale (Face, Legs, Activity, Cry, Consolability), a widely recognized tool for assessing pain in children, and the children's self-reported pain scores. The results of the study revealed that children who received local anesthesia using the device method had significantly lower mean pulse rates, indicating reduced anxiety. Additionally, both FLACC scores and self-reported pain scores were lower in the group treated with the device compared to those who received the conventional injection. These findings suggest that the device method was not only more effective in alleviating pain and anxiety but also contributed to better overall behavior during the procedure. In conclusion, the study demonstrated that the child-friendly device method offers a superior approach to pain management, anxiety reduction, and behavioral control in pediatric patients aged 6–11 years compared to the traditional injection method. Moreover, the device is simple, cost-effective,

and well-suited for use in pediatric settings, making it a valuable tool for healthcare providers when administering local anesthesia to young patients.

28. Bhawana, Apoorva, Gadre KS & Nasti SA (2019) [46] evaluated and compared the pain experienced during needle insertion and the administration of local anesthesia on the palate using VibraJect™ (a vibrating attachment to the conventional syringe) versus a conventional syringe alone. The primary objective was to assess the efficacy of the VibraJect™ device in reducing pain and discomfort during palatal block anesthesia and to measure procedural anxiety in patients undergoing dental treatment. A total of 50 patients requiring bilateral posterior teeth treatment were enrolled in this split-mouth, randomized controlled clinical study. Each patient received local anesthesia using both techniques—VibraJect™ on one side and the conventional syringe on the other—in separate sessions. Pain relief was recorded using the Facial Visual Analogue Scale (VAS) at various time points: immediately postoperatively, at the 2nd, 4th, and 8th hours, and on postoperative day 1. Additionally, the study noted when patients first complained of unbearable pain, at which point they were administered 20 mg of oral piroxicam as rescue medication. The results showed that there was no statistically significant difference in pain scores between the two techniques, both during needle insertion and while administering local anesthesia. Patients reported similar levels of discomfort with both methods, suggesting that VibraJect™ did not provide a notable advantage in terms of pain reduction. In conclusion, the study found that the traditional syringe method was generally preferred over VibraJect™, primarily because the latter requires an additional attachment to the conventional syringe, without demonstrating clear clinical benefits in terms of pain relief. The authors noted that the clinical efficacy of VibraJect™ remains controversial, as its pain-reducing potential during palatal anesthesia was not supported by significant findings in this study.
29. Robertson M, Araujo M & Innes N (2019) [47] investigated distraction techniques to manage dental anxiety & fear in patients under 18 years old compared to no intervention. Data were extracted by two independent reviewers using standardised data tables. Twenty-one RCTs were included in this systematic review. Participant ages ranged from 4 to 16 years old. Distraction

techniques included use of audio and audio-visual techniques, instrument camouflage, biofeedback therapy, dental operating microscope and toys. Data were collected pre- and post-dental procedures including: dental examination; prophylaxis; local anaesthetic administration; restoration placement; exodontia; and placement of rubber dam. Within studies, between one and six instruments were used to measure children's anxiety and dental fear. Objective measures with pulse oximeters and blood pressure cuffs were used most frequently. Authors concluded that the studies included in this systematic review suggest that distraction techniques might be useful to control children's anxiety and fear during dental appointments, however, the certainty of evidence is very low. There are no contraindications for the use of distraction techniques during children's and adolescents' dental appointments.

30. Khandelwal M, Shetty RM & Rath S (2019) [48] compared and evaluated the effectiveness of various distraction techniques in managing pediatric dental patients. Eighty healthy children selected for the study were randomly divided into 4 groups with 20 children in each group. Group I was termed as the control group; in group II, the audio distraction technique was used. Group III received audio–video distraction (AVD) by means of a chair-mounted audio–video device and group IV received AVD by means of a ceiling-mounted television. Each child had four dental visits. Child's anxiety in each visit was assessed using four parameters: RMS pictorial scale (RMS-PS), Venham picture test (VPT), pulse rate, and oxygen saturation. Results showed that ceiling-mounted AVD was found to be the most effective in reducing the anxiety followed by chair-mounted AVD. Audio distraction was found to be the least effective but was better than the control group. Authors concluded that the AVD technique is simple, passive, and noninvasive means of behaviour management and can be used alternatively in managing anxious pediatric dental patients.

31. Sivakumar P & Gurunathan D (2019) [49] evaluated the behavior of pediatric patients aged 7 to 17 years in response to various dental treatment procedures. A total of 50 children were categorized according to Frankl's behavior rating scale, and their behavior was recorded before, during, and after treatment. The results revealed that children undergoing extractions and

pulpectomies exhibited the most uncooperative behavior. Specifically, 60% of patients undergoing extractions and 45% of those receiving pulp therapy displayed negative behavior (rated as 2) during the treatment. The authors concluded that invasive procedures, such as extractions and pulpectomies, tend to elicit negative behavior in pediatric patients, particularly during the actual treatment. This highlights the need for dental practitioners to implement strategies to manage anxiety and promote cooperation during these more invasive procedures, ensuring a more positive experience for young patients.

32. Padminee K & Hemalatha R (2019) [50] assessed the effectiveness of DIY camouflaged syringes by comparing it with that of conventional syringes through evaluation of behaviour and dental anxiety in 6–10-year-old children while administering LA. A group of 20 children aged 6-10 years were randomly divided into two groups. Both the groups received local anaesthesia using camouflaged syringes and conventional syringes in two different appointments as per the order of intervention allotted in the cross over trial. The heart rates were measured using pulse oximeter and behavioural assessment was done using Faces, Leg, Activity, Cry, Consolability (FLACC) scale. Results revealed that the mean FLACC score were 1.1 with camouflage syringe group and 1.75 with conventional syringe. FLACC scores were more with conventional syringe indicating that camouflage syringes are effective in reducing anxiety. However, this difference was not found to be statistically significant. Heart rate values increased in both groups but the magnitude of the rise in value was found to be more with conventional syringes. The increase in the mean heart rate was more with use of conventional syringe than camouflage syringes and the difference was also found to be statistically significant. The authors finally concluded that camouflaged needles can better reduce anxiety levels when compared to the conventional syringes.

33. Goenka A, Das S, Saikia AM & Hazarika M (2019) [51] compared and evaluated the pain, anxiety and comfort in paediatric patients undergoing local anesthesia using Vibraject syringe system and Camouflage syringe with Conventional Cartridge based syringe. 120 children with 40 in each group, between age group of 5-12 years were taken for the study. On evaluating the

pain perception and anxiety using subjective evaluation (Wong Baker's scale and Venham's rating scale), Group II (Vibraject) was found to be the most effective as compared to Group I (Camouflage) and Group III (Conventional) in both 5-8 years and 9-12 years. But when physiologic parameters like blood pressure, pulse rate were measured, Group II (Vibraject) showed increase in anxiety of patients while Group I (Camouflage) showed decrease in anxiety and pain perception in 9-12 years age group. In Group I, Reduction in pain perception and anxiety were observed significantly in 9-12 years age. This could be because they are more easily distracted and the toy-like appearance of the camouflaged syringe takes away the fear-provoking stimuli of a conventional syringe It provoked anxiety in 5-8 years of age due to unacceptability of sight of sleeve. In Group II, Vibraject provides reduction in anxiety and pain perception in comparison to the conventional injection technique and Camouflage syringe in clinical dental procedures in children of 5-12 years of age. While the role of physiological parameters in pain perception was inconclusive, Vibraject may be a promising alternative method of delivering local anesthesia in children. The authors thus concluded that need of masking techniques for LA administration either by using vibratory devices, camouflaging, application of topical anesthetics and effective distraction methods reduce pain and anxiety in paediatric patients

34. Aggarwal K, Lamba AK, Faraz F, Tandon S & Makker K (2018) [52] aimed to compare the levels of anxiety and pain perceived during anesthesia delivery using conventional syringe systems and computerized systems across various stages of nerve block administration. A total of 100 patients aged 6-9 years, requiring bilateral local anesthesia (LA) participated in the study. For each patient, one side was anesthetized with the conventional syringe system, while the contralateral side was treated with the computerized controlled local anesthetic delivery (CCLAD) system, administered during two separate appointments. Patient's anxiety levels were evaluated using a 5-point Venham's Anxiety Scale and their pain was assessed using the Visual Analogue Scale (VAS) at four critical stages: needle insertion, delivery of the anesthetic solution, immediately following the injection, and after the periodontal procedure.

Additionally, each patient's preference for their preferred anesthesia delivery system for future treatments was documented. The results revealed significantly lower anxiety levels when using the CCLAD system as compared to the conventional syringe. Similarly, the mean VAS scores indicated significantly less pain during the delivery of the anesthetic solution, immediately after injection, and at the end of the periodontal procedure with the CCLAD system. However, pain perception during needle insertion was comparable between the two systems, showing no statistically significant difference. Interestingly, while the mean VAS score for needle insertion was slightly lower with the CCLAD system, the difference was not statistically significant. This could potentially be attributed to the use of needles of the same size in both systems, minimizing variability in pain perception during this stage. Overall, 64.4% of patients expressed a preference for the CCLAD system for future anesthesia delivery, emphasizing its acceptability among patients. The authors concluded that the results of this study underscore the advantages of the CCLAD system over conventional syringes for administering local anesthesia. The significantly lower anxiety levels, reduced pain perception across key stages, and higher patient preference suggest that the CCLAD system is a more effective and comfortable alternative for delivering pain-free dental treatment.

35. Melwani AM et al (2018) [53] compared the efficacy of a camouflaged syringe and conventional syringe on behavior and anxiety in 6–11-year-old children during local anesthesia administration. The study involved two sessions wherein all the children were injected using conventional and camouflaged syringes in separate sessions. Their behavior was assessed using the Faces, Legs, Activity, Cry, Consolability (FLACC) behavior pain scale and anxiety was assessed by measuring changes in pulse rate. Patient and operator preferences were also compared**.** The mean FLACC scores in both groups were lower when camouflaged syringes were used indicating a better behavior. The FLACC scores and Pulse Rate were not significantly different between both groups when conventional and camouflaged syringes were used. A statistically significant correlation was noted between patient and operator preferences in group 2. Younger children, preferred the camouflaged alternative possibly because they are

more easily distracted and the toy-like appearance of the camouflaged syringe takes away the fear-provoking stimuli of a conventional syringe. An older child would probably be less easily distracted with a camouflaged syringe as compared to a younger child. This could explain the lower preference rate of camouflaged syringe in group 2 than group 1. It was therefore concluded that the use of camouflaged syringes for anesthesia was demonstrated to be effective in improving the behavior of children and decreasing their anxiety, and is therefore recommended as an alternative to the use of conventional syringes for local anesthesia.

36. Tandon S et al (2018) [54] compared the effectiveness of lignocaine jelly and mucosal vibration in reducing pain during local anesthesia administration in pediatric dental patients. Thirty children aged 6 to 11 years, requiring bilateral anesthesia for dental treatment in the mandible, participated in the study. Pain levels were assessed using the Wilcoxon signed-rank test at the time of injection, utilizing the Sound, Eye, Motor (SEM) scale as an objective measure and the Facial Pain Rating (FPR) scale as a subjective measure. The injections were administered by a trained assistant who was blinded to the procedure to ensure unbiased results. The findings indicated that local anesthetic injections accompanied by mucosal vibration resulted in significantly less pain ($p = 0.001$) compared to injections without mucosal vibration. This suggests that mucosal vibration is an effective method for reducing pain intensity during local anesthetic injections in pediatric dentistry, offering a valuable tool for enhancing patient comfort during dental procedures.

37. Saad NM, El Agamy RA & Abdellatif AM (2017) [55] evaluated the effect of the vibration-assisted syringe on pain perception in children during different intra-oral injections of local anesthesia, as well as, assessment of anxiety expressed by children receiving different intra-oral injections using vibration-assisted syringe. study was conducted as a prospective randomized controlled clinical trial. A total number of 120 children aged 4-8 years. The children were assigned into four equal groups (30 children each) according to the type of intra-oral injection needed for their treatment; Group I: children underwent upper posterior buccal infiltration, Group II: children underwent inferior alveolar nerve block, Group III: children

underwent upper anterior infiltration, and Group IV: children underwent posterior palatal infiltration. This study was conducted considering the split mouth design. Results revealed that on comparing the difference in pain perception by VAS, it was significantly lower in Vibraject-assisted injections in groups I, III, and IV. On comparing the difference in anxiety by FAS, it was significantly lower in Vibraject-assisted injections only in group IV subjects. Authors concluded that Vibraject provides less pain in comparison to conventional injection. Some of the children were less anxious when injected by Vibraject-assisted syringe in comparison to the conventional syringe. Vibraject may be a promising method of delivering local anesthesia in children.

38. Ramar K et al (2016) [56] conducted a study to assess the impact of audio-analgesia—using sound or music as a distraction technique—on pain perception in children aged 6 to 12 years during dental treatment. A total of 40 children were selected for the study and were randomly divided into two groups. The study group consisted of children who received audio-analgesia during the dental procedure, while the control group underwent treatment without the use of audio-analgesia. To measure the level of pain experienced by the children, Venham's pain rating scale was used, a well-known tool for assessing dental pain in pediatric patients. The results revealed a statistically significant difference in pain levels between the two groups. Children in the study group, who listened to music or other calming audio during the procedure, reported notably lower pain scores compared to those in the control group. In conclusion, the findings suggest that the distraction method of audioanalgesia effectively reduces pain perception in children undergoing dental procedures. The use of audioanalgesia not only lowers the sensation of pain but also promotes a more positive attitude towards dental treatments in children aged 6 to 12 years. Therefore, incorporating music or sound during dental procedures can be a simple, non-invasive, and effective strategy for improving the overall experience for young patients.

39. Chaudhry K, Shishodia M, Singh C & Tuli A (2015) [57] evaluated and compared the pain perception during dental procedures using the Vibraject™ device versus the conventional

injection technique in pediatric patients. A total of 20 children, aged 8 to 14 years, were selected for this clinical trial. During their first appointment, local anesthesia was administered using a conventional syringe, while at the second appointment, Vibraject™ was used on the opposite side of the same dental arch. To assess the children's pain response, two different pain scales were employed: The Visual Analog Scale (VAS) and the Faces Pain Rating Scale (FRS). These scales provided both objective and subjective measurements of the children's pain experiences with each technique. The study found a statistically significant difference in pain perception between the two techniques, with children reporting lower pain scores on both the VAS and FRS when Vibraject™ was used. However, when physiological parameters—such as heart rate, blood pressure, and body temperature—were monitored at various intervals during the procedures, no statistically significant differences were observed between the two techniques. This suggests that while Vibraject™ helped reduce perceived pain, it did not lead to significant changes in physiological stress indicators. In conclusion, the study demonstrated that the Vibraject™ device provides a less painful experience for children during local anesthetic injections compared to the conventional injection technique. Although it did not significantly impact physiological parameters, Vibraject™ offers a more comfortable alternative for pain management in clinical pediatric dentistry, making it a valuable tool for improving the patient experience during dental procedures.

40. Nasehi A, Bhardwaj S, Kamath AT, Gadicherla S & Pentapati KC (2015) [58] evaluated clinical pain during local anesthetic injections using an intra-oral vibration device. A total of 99 subjects participated, including 39 females, and 256 local anesthetic injections were administered, with each subject receiving at least one pair of similar injections. The comparison of mean Visual Analog Scale (VAS) scores for anticipated pain showed that the group receiving injections without vibration reported significantly higher pain scores across all types of nerve blocks compared to the vibration group. Similarly, the actual pain scores were also significantly higher in the non-vibration group for all nerve blocks. In the non-vibration group, there was no significant difference in mean VAS scores between anticipated and actual pain for inferior

alveolar (p = 0.673), infra-orbital (p = 0.175), and palatal (p = 0.343) injections. Conversely, in the vibration group, the mean VAS score for actual pain was significantly lower than the anticipated pain score for both inferior alveolar and infra-orbital injections (p = 0.002). The authors concluded that the use of an intra-oral vibration device resulted in a significant reduction in pain experienced during local anesthetic injections. This finding suggests that vibration technology may enhance patient comfort and reduce perceived pain during dental procedures.

41. Asokan A, Rao AP, Mohan G, Reddy NV & Kumar K (2014) [59] compared the pain perception of children to local anesthesia (LA) using 26 gauge and 30-gauge needles with different age, sex, and visits. A total sample of 30 children (16 boys and 14 girls) who were undergoing routine dental procedures was selected for the study. Children were assigned into two groups: Group A: 12 children aged 6-8 years Group B: 18 children aged 9-12 years. Informed consents were obtained from parents. The objective and subjective behavioural parameters were evaluated. Study revealed that the mean difference was found to be statistically significant (P = 0.001). The mean pain score in fi rst visit for patients who received LA with 30 -gauge needles was found to be 2.00, whereas for second visit was found to be 2.61. The mean pain difference was found to be statistically significant (P = 0.01). No significance was seen in relation to age and gender. Authors concluded that the pain due to injection penetration might be controlled by using thinner gauge needles in spite of difference in pain perceptions. During a child's fi rst dental visit, use of less pain provoking armamentarium would aid in relieving anxiety and desensitize the patient slowly.

42. Chandrasekaran J, DP, S, MS, Ahmed A & Kumarasamy B (2014) [60] evaluated the efficacy of VibraJect™, a vibrating attachment for syringes, in comparison to the conventional injection technique in reducing pain during dental procedures. The total sample consisted of 37 subjects, and the effectiveness of both methods was assessed based on self-reported pain scores. Out of the total participants, 35 subjects reported higher pain scores with the conventional injection technique compared to VibraJect™, showing a statistically significant difference (Z = -5.5, p =

0.00). Additionally, 14 subjects also reported increased pain with the conventional method compared to VibraJect™. The two-tailed sign test further confirmed this finding, with a p-value of 0.04, indicating a statistically significant difference between the two techniques. The study concluded that VibraJect™ significantly reduced pain, both during the insertion of the needle and during the deposition of the anesthetic solution, when compared to the traditional injection technique. This suggests that VibraJect™ may offer a more comfortable and less painful alternative for administering local anesthesia in dental procedures.

43. Bansal N, Saha S, Jaiswal JN & Samadi F (2014) [61] evaluated and compared effectiveness of transcutaneous electrical nerve stimulator (TENS) and comfort control syringe (CCS) in various pediatric dental procedures as an alternative to the conventional method of local anesthesia (LA) administration. Ninety healthy children having at least one deciduous molar tooth indicated for extraction in either maxillary right or left quadrant in age group of 6 to 10 years were randomly divided into three equal groups having 30 subjects each. Group I: LA administration using conventional syringe, group II: LA administration using TENS along with the conventional syringe, group III: LA administration using CCS. After LA by the three techniques, pain, anxiety and heart rate were measured. Results revealed that the mean pain score was maximum in group I followed by group II, while group III revealed the minimum pain, where LA was administered using CCS. Mean anxiety score was maximum in group I followed by group II, while group III revealed the minimum score. Mean heart rate was maximum in group I followed in descending order by groups II and III. The study supports the belief that CCS could be a viable alternative in comparison to the other two methods of LA delivery in children.

44. Khatri A & Kalra N (2012) [62] assessed pain in children aged 3 to 14 years in a dental setting and to compare two pain measurement techniques: the Visual Analogue Scale (VAS) and the Wong-Baker Faces Pain Rating Scale (WBFPS). The researchers sought to determine how these scales correlated with one another. The analysis revealed a highly significant difference in VAS scores between the youngest group (Group I) and the oldest group (Group III), but not between

Group I and the middle age group (Group II). The ANOVA results indicated a p-value of 0.465 regarding differences between sexes, suggesting no significant variation. The interaction between sex and age group also showed no significance (p = 0.751). In terms of WBFPS scores, the mean score for Group I was 4.3 for males and 4.8 for females, indicating that both genders experienced moderate pain. For Group II, the mean scores were 3.3 for males and 3.2 for females, while in Group III, the mean scores were 3.1 for males and 3.2 for females, reflecting a slight decrease in pain perception with age. The study found no statistically significant differences in pain scores between genders across all age groups using the VAS. However, the authors concluded that the Wong-Baker Faces Pain Rating Scale (WBFPS) was more sensitive than the VAS in capturing pain levels. Furthermore, the communication abilities of boys and girls were similar across all age groups. Notably, pain threshold appeared to decline with increasing age, suggesting that as children grow older, pain management becomes more effective.

45. Dhindsa A, Pandit IK, Srivastava N & Gugnani N (2011) [63] evaluated the effectiveness of Transcutaneous Electrical Nerve Stimulation (TENS) in reducing pain during various minor pediatric dental procedures and to compare its efficacy with 2% lignocaine. A total of 180 patients, aged 5 to 14 years with ASA Grade 1 status and no history of allergic reactions to local anesthesia, were selected and randomly divided into two equal groups of 90 patients each. Each group was further divided into three subgroups of 30 patients requiring endodontic procedures. The effectiveness of TENS and 2% lignocaine was assessed using Visual Analog Scale (VAS), Visual Pain Scale (VPS), and Likert's scale to measure pain perception during the procedures. ANOVA analysis revealed no statistically significant difference in pain scores between the two groups (P > 0.05) across the various dental procedures assessed. Despite the lack of significant differences in pain reduction, the study concluded that TENS provides notable advantages. It is effective in alleviating the fear of pain associated with dental injections, is non-invasive, and is safe to handle. Additionally, TENS avoids the inconvenience of post-operative anesthetic effects, helps maintain infection control, and eliminates the potential side effects commonly

associated with injectable anesthetic agents. In summary, while both TENS and 2% lignocaine were found to be effective in managing pain, TENS offers several benefits that make it a valuable alternative in pediatric dentistry, particularly in reducing anxiety related to dental injections.

46. Roeber B, Wallace DP, Rothe V, Salama F & Allen KD (2011) [64] conducted a study to evaluate the effectiveness of VibraJect™, a vibrating attachment for traditional syringes, in reducing pain-related disruptive behavior and self-reported pain in children receiving local anesthesia during routine dental procedures. This randomized, controlled, single-blinded study involved 90 children who were administered local anesthesia for restorative dental treatments. The researchers employed a two-way analysis of variance (ANOVA) and two-tailed, between-subject t-tests to analyze the data, focusing on multiple measures of pain, including self-reported pain intensity, observed disruptive behavior related to pain, and subjective assessments provided by the dentists. Despite the theoretical benefits of the VibraJect™ device, the results indicated no statistically significant differences in pain relief between the VibraJect™-assisted injections and traditional syringe injections. None of the measured parameters—self-reported pain levels, observed disruptive behavior, or dentist evaluations—showed a marked improvement when using the VibraJect™. In conclusion, the study found that VibraJect™ did not provide any significant advantages over the conventional method for administering local anesthesia in children. The device did not contribute to a reduction in pain perception, disruptive behavior, or improve the overall experience of receiving dental injections in pediatric patients. Thus, VibraJect™ may not offer any substantial clinical benefit in the pediatric population studied.

47. Saijo M, Ito E, Ichinohe T & Kaneko Y (2005) [65] evaluated injection pain when the Vibraject device was used in conjunction with an automated electric syringe and a 33-gauge dental needle under single-blind randomized conditions. Ten volunteers received injections into the alveolar mucosa adjacent to the root apex of the maxillary lateral incisor, with Vibraject randomly applied to either the left or right side. The results showed no statistically significant decrease in

pain scores during needle insertion or anesthetic injection, indicating that the Vibraject device did not effectively reduce injection pain in this context. The authors concluded that Vibraject does not alleviate injection pain when applied to blinded patients using an automated electric syringe and a 33-gauge dental needle. This finding suggests that further research may be needed to explore alternative methods for pain management during dental injections.

# MATERIAL AND METHOD

**ARMAMENTARIUM**

1. Local Anesthesia (Lignox 2% A, Indoco Warren, India)
2. Tropical Anaesthetic Gel (Lignospan-O, Septodont Healthcare India Pvt.Ltd)
3. 2% lidocaine hydrochloride Cartridges (Lignospan Special, Septodont Healthcare India Pvt.Ltd)
4. Pulse-oximeter (AmbiTech, Phoenix Innovative Healthcare Manufactures Pvt. Ltd.)
5. Conventional Syringe, (Single use 2ml syringe with 27G needle) (Dispovan, Hindustan Syringes & Medical Devices Ltd. India)
6. StarPen Anesthetic Device (Guilin Woodpecker Medical Instrument Co.,Ltd., P.R.China)
7. Vibraject Device (A.Titan, MiltexInc LLC., York, PA, USA)

# METHODOLOGY

## STUDY SETTING

The study was conducted in the Department of Pediatric and Preventive Dentistry at Santosh Dental College and Hospital, Santosh Deemed to be University, Ghaziabad, NCR Delhi. It was designed as a Randomized, Parallel-group design, Controlled Trial to evaluate the efficacy of StarPen compared to Vibraject and a Conventional Syringe. The study was completed within a span of two years.

## SAMPLE SIZE

A total of 150 children, aged between 6 and 10 years, were selected from the dental OPD of the Department of Pediatric and Preventive Dentistry at Santosh Dental College, Ghaziabad, NCR Delhi. The children were randomly assigned to three groups using GraphPad Prism.

## SAMPLE GROUP

The selected children were divided into three equal groups, with 50 children in each group (n=50).

**Group A**: StarPen (n=50)

**Group B**: Vibraject (n=50)

**Group C**: Conventional Syringe (n=50) (Control)

## INCLUSION CRITERIA

1. Children aged between 6 and 10 years were selected.
2. Only those receiving local anesthesia for the first time were included.
3. Patients requiring an Inferior Alveolar Nerve Block were considered.
4. Children exhibiting Frankl's definitely positive or positive behavior were included.

## EXCLUSION CRITERIA

1. Patients who had previously experienced local anesthesia administration.
2. Children with acute or chronic inflammation or an abscess at the injection site.
3. Patients with a history of traumatic or painful dental experiences.
4. Patients with underlying medical conditions or developmental anomalies.
5. Children who had taken any analgesic medication in the past 24 hours.
6. Patients with a known history of allergy to local anesthesia.

## METHODOLOGY

### Study Design and Participant Selection

A total of 150 pediatric patients, aged 6–10 years, were recruited from the Outpatient Department of Pediatric and Preventive Dentistry at Santosh Dental College and Hospital, Ghaziabad, Delhi-NCR. Inclusion criteria required participants to exhibit "positive" or "definitely positive" behavior according to Frankl's Behavior Rating Scale **(Table 1)**.[66] Prior to enrollment, parents or legal guardians received a comprehensive explanation of the study objectives and methodology, following which written informed consent **(Annexure II)** was obtained.

To ensure familiarity with the clinical environment and reduce anxiety, the 'Tell-Show-Do' technique was implemented before the procedure. Baseline anxiety levels were assessed using Venham's Anxiety Scale **(Table 2)** [67], and the child's resting pulse rate was recorded with a pulse oximeter.

### Anesthetic Techniques and Randomization

Participants were randomly allocated into three equal groups (n = 50), each receiving local anesthesia through a distinct delivery method:

- **Group 1:** Starpen (computer-controlled local anesthetic delivery system)
- **Group 2:** Vibraject (vibrating syringe attachment)
- **Group 3:** Conventional syringe

A topical anesthetic gel (20% benzocaine) was applied for one minute on a dried mucosal surface before the injection. All injections were administered by a single experienced clinician to ensure standardization. The anesthetic agent used was 2% lidocaine hydrochloride with 1:80,000 epinephrine (Lignospan Special), with a standardized volume of 1.5 mL across all groups.

- **Starpen Group:** The anesthetic was delivered using a hybrid speed protocol—low speed for the first 10 seconds, followed by high speed for the next 50 seconds—with an automatic aspiration mode via a 30-gauge needle for an inferior alveolar nerve block.
- **Vibraject Group:** A conventional syringe with a 27-gauge needle, fitted with the Vibraject attachment (a battery-operated vibrating device), was used to introduce vibratory stimulation during administration.
- **Conventional Syringe Group:** Local anesthesia was delivered manually without adjunctive technology.

**Outcome Measures and Data Collection**

Pain perception during injection was assessed using the Face, Legs, Activity, Cry, Consolability (FLACC) scale **(Table 3)**.[68] Post-injection anxiety levels were reassessed using Venham's Anxiety Scale, and physiological responses were evaluated by recording the post-injection pulse rate with a pulse oximeter. Any immediate adverse reactions were noted, and post-anesthesia care instructions were provided to the parents.

All collected data, including pain scores, anxiety levels, and physiological responses, were systematically documented for statistical analysis to compare the efficacy and patient comfort associated with the three anesthetic delivery techniques.

**SCALES USED**

**Table 1: Assessment of Behavior using Frankl's Behavior Rating Scale [66]**

| Frankl's Behavior Ratings | Behavior (Symbol) | Definition |
|---|---|---|
| 1 | Definitely Negative (- - ) | Refuses treatment, cries forcefully, extremely negative behavior associated with fear. |
| 2 | Negative (-) | Reluctant to accept treatment and displays evidence of slight negativism. |
| 3 | Positive (+) | Accepts treatment, but if the child has a bad experience during treatment may become uncooperative. |
| 4 | Definitely Positive (+ + ) | Unique behavior, looks forward to and understands the importance of good preventive care. |

**Table 2: Assessment of Anxiety using Venham's Anxiety Scale [67]**

| Score | Definition |
|---|---|
| 0 - Relaxed | Smiling, willing to cooperate, able to converse, displays behavior desired by the dentist. |
| 1 - Uneasy | Concerned, may protest briefly, hands remain down or partially raised, capable of cooperating. |
| 2 – Tense | Tone of voice, questions, and answers reflect anxiety, during stressful procedure, verbal protest, crying, hands raised with tension but not interfering very much. Complies with request to cooperate. |
| 3 - Reluctant | Prominent verbal protest, crying, using hands to try to stop procedure, treatment proceeds with difficulty. |
| 4 - Interference | General crying, body movements sometimes needing physical restraint. Protest & disrupts procedure. |
| 5- Out of control | Hard loud swearing, screaming, unable to listen, trying to escape. |

**Table 3: Assessment of Pain using Face, Legs, Activity, Cry, Consolability (FLACC) Scale [68]**

| FLACC Scale | 0 | 1 | 2 |
|---|---|---|---|
| Face | No particular expression or smile | Occasional grimace or frown, withdrawn, disinterested | Frequent to constant frown, clenched jaw, quivering chin |
| Legs | No position or relaxed | Uneasy, restless, tense | Kicking or legs drawn up |
| Activity | Lying quietly, normal position, moves easily | Squirming, shifting back and forth, tense | Arched, rigid or jerking |
| Cry | No crying | Moans or whimpers, occasional complaints | Crying steadily, screams or sobs, frequent complaints |
| Consolability | Content, relaxed | Reassured by occasional touching, hugging, or being talk to, distractible | Difficult to console or comfort |

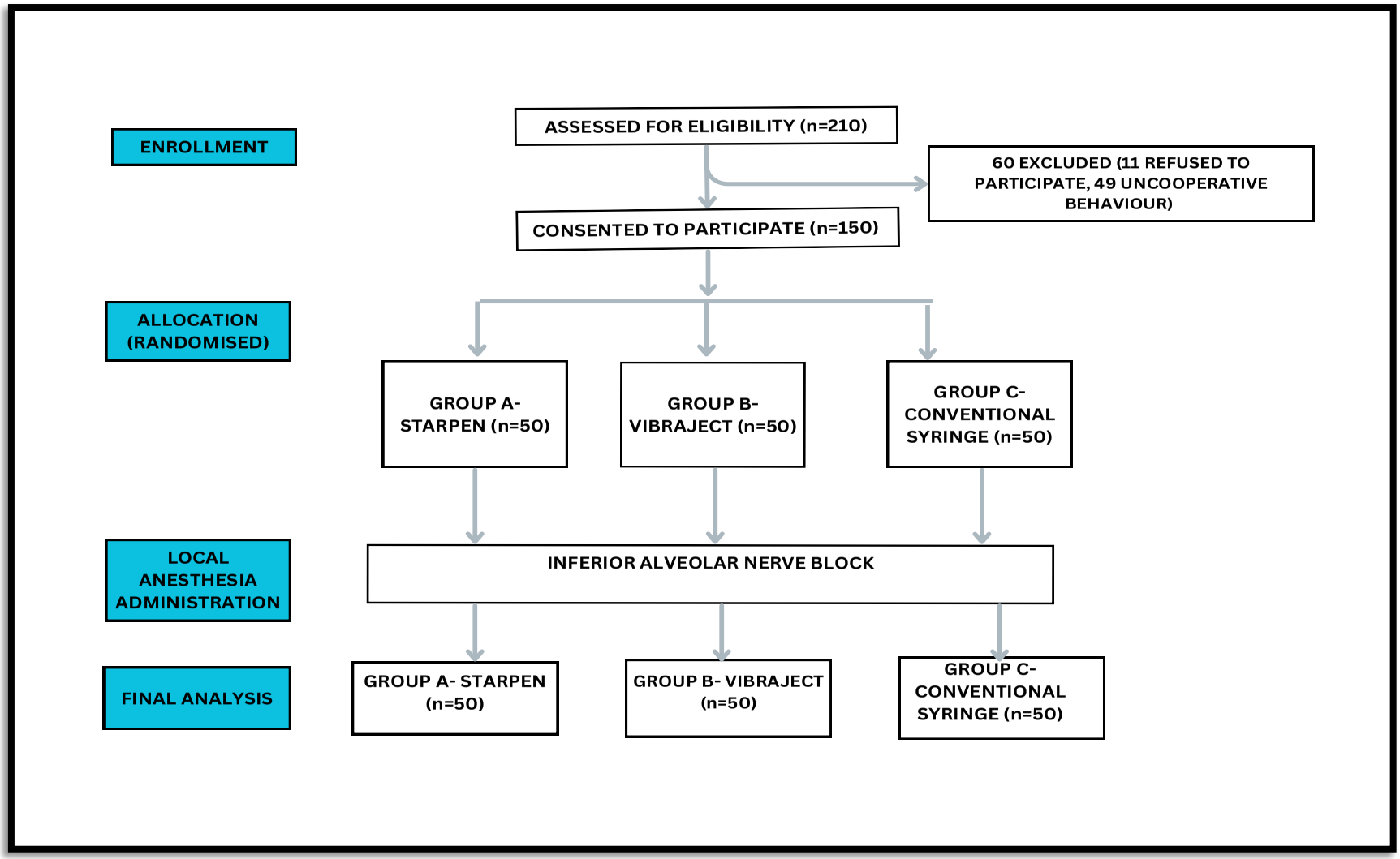
**Inference for FLACC Score**

0 = Relaxed and comfortable

1-3 = Mild discomfort

4-6 = Moderate pain

7-10 = Severe discomfort/pain




Flowchart 1: A diagrammatic representation of the trial according to CONSORT

# COLOUR PLATE 1

## ARMAMENTARIUM

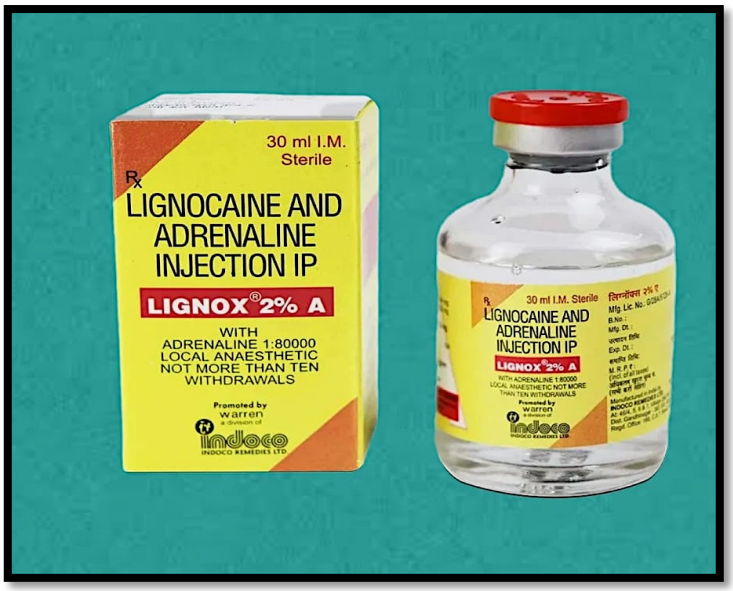



**Fig 1: Local Anesthesia (Lignox 2% A, Indoco Warren, India)**

**Fig 2: Tropical Anesthetic Gel (Lignospan-O, Septodont Healthcare India Pvt. Ltd.)**

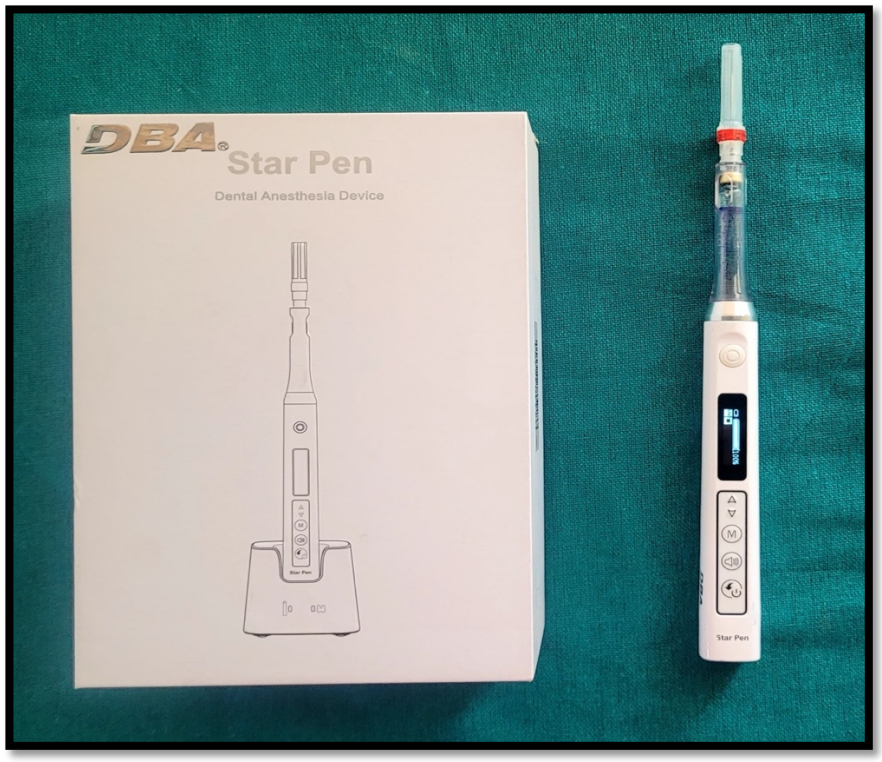
# COLOUR PLATE 1

Lignospan Special
Lidocaine hydrochloride 2%
and adrenaline (epinephrine) injection 1:80,000
Solution for injection
INFILTRATION OR NERVE BLOCK INJECTION
This product contains sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.
50 dental cartridges of 1.8 ml.
septodont

**Fig 3: Local Anesthetic Cartridge (Lignospan Special- Septodont)**

**Fig 4: Pulse-oximeter (AmbiTech, Phoenix Innovative Healthcare Manufactures Pvt. Ltd.)**

**Fig 5: 2ml Conventional Syringe with 24G needle (Shinrai, NIPRO Single-use Syringe)**



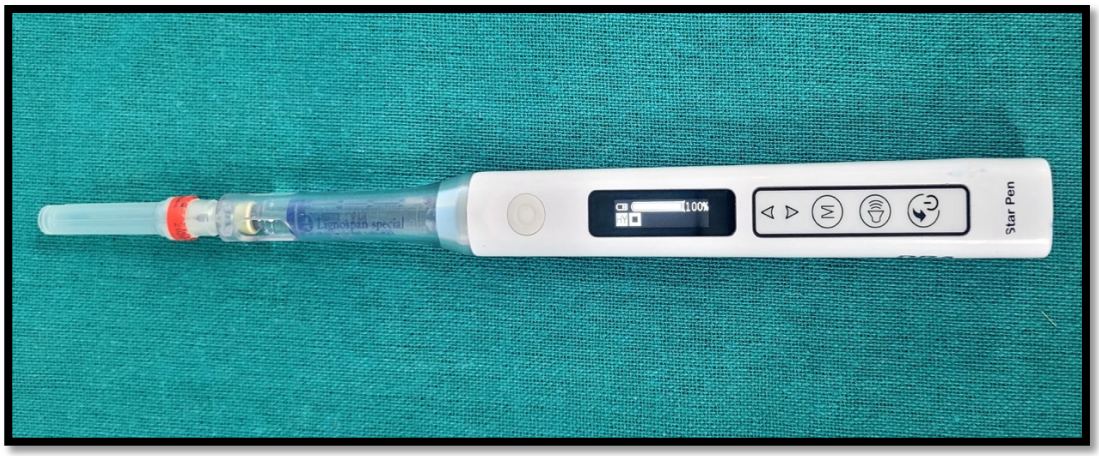




**Fig. 6: StarPen Anesthetic Pen (Guilin Woodpecker Medical Instrument Co., Ltd., P.R.China)**

## COLOUR PLATE 1

**Fig.7 : Vibraject (A. Titan, Miltex LIC., York, PA, USA)**

# COLOUR PLATE 2

## INTERVENTION- GROUP A- STARPEN

**Fig. 8: Administration of Inferior Alveolar Nerve Block using StarPen**

# COLOUR PLATE 2

## INTERVENTION- GROUP B- VIBRAJECT

**Fig. 9: Administration of Inferior Alveolar Nerve Block using Vibraject**

## COLOUR PLATE 2

**INTERVENTION- GROUP C- CONVENTIONAL SYRINGE**

**Fig. 10 : Administration of Inferior Alveolar Nerve Block using Conventional Syringe**

# STATISTICAL ANALYSIS

The statistical analysis for this study was done using Statistical Package for Social Sciences Software (SPSS), Version 30.0. The statistical parameters used were the mean, standard deviation, paired T-test, and ANOVA test followed by Post-hoc Bonferroni. The data were presented as count (n), mean ($\bar{x}$), and statistical significance (p-value).

**Mean/ Average:**

The arithmetic mean, often referred to as the average or simply the mean, is calculated by summing all observed values and dividing the total by the number of observations.

The mean and median are measures of the position of the middle of the distribution, which we call the central tendency.

$$\mathbf{X = \Sigma\ X / Number\ of\ observations\ (n)}$$

**Standard Deviation:**

Standard deviation, a commonly employed indicator of variability or spread, is defined as the square root of the variance within a statistical population, dataset, or probability distribution. It shows how much variation there is from Average or Mean.

$$\sigma = \sqrt{\frac{\sum(x_i - \mu)^2}{N}}$$

**ANOVA with Post-hoc Bonferroni Comparison:**

In a one-way ANOVA, the F-statistic is used to determine whether there are any significant differences among the means of the J groups, essentially testing the hypothesis that all treatment outcomes are equal.

A relevant F value implies that the means have differences, but it does not tell you where those differences are, e.g. the mean of group 1 might be different from the mean of group 2, but not different from the mean of group 3.

The Bonferroni test is used in statistical analysis as a form of multiple comparison test. Inevitably, a result could occur while performing a hypothesis test with several comparisons that appears to show statistical significance in the dependent variable, even when there is none.

Basically, each of the significance levels of the LSD test is multiplied by the number of tests conducted, i.e. (J) J*(J-1)/2. If this value is greater than 1, then a degree of significance of 1 is added. So, for example, the LSD test reports that at the .009574 stage, the difference between groups 1 and 2 is important. The Bonferroni adjustment multiplies this by 6 (when there are 4 groups, the number of pairwise comparisons) and reports a level of significance of 6 * .009574 = .057442. Note that this is greater than .05, but it is not considered significant to become the difference between groups 1 and 2 (hence no * in the mean column of the difference).

**Paired T-Test:**

The t distribution is used to find confidence intervals for means estimated from a small sample with Normal distribution. The population mean is unknown and we wish to estimate it using a 95% confidence interval. The usual application of this is to calculate the differences between measurements made on the same or on matched pairs of subjects. In this application the one sample t test is also known as the paired t test.

**Level of significance (p-value):**

The p-value represents the likelihood of observing a result as extreme as, or more extreme than, the one obtained, under the assumption that the null hypothesis is true.
When evaluating a hypothesis, the highest probability at which one is willing to accept the risk of making an incorrect decision is referred to as the test's level of significance. Two tailed P values were taken.

P> 0.05 – Non significant

P≤ 0.05 – Significant

p≤ 0.01 – Highly significant

p≤ 0.001 - Very highly significant

# RESULTS

**Pain Assessment- FLACC Score**

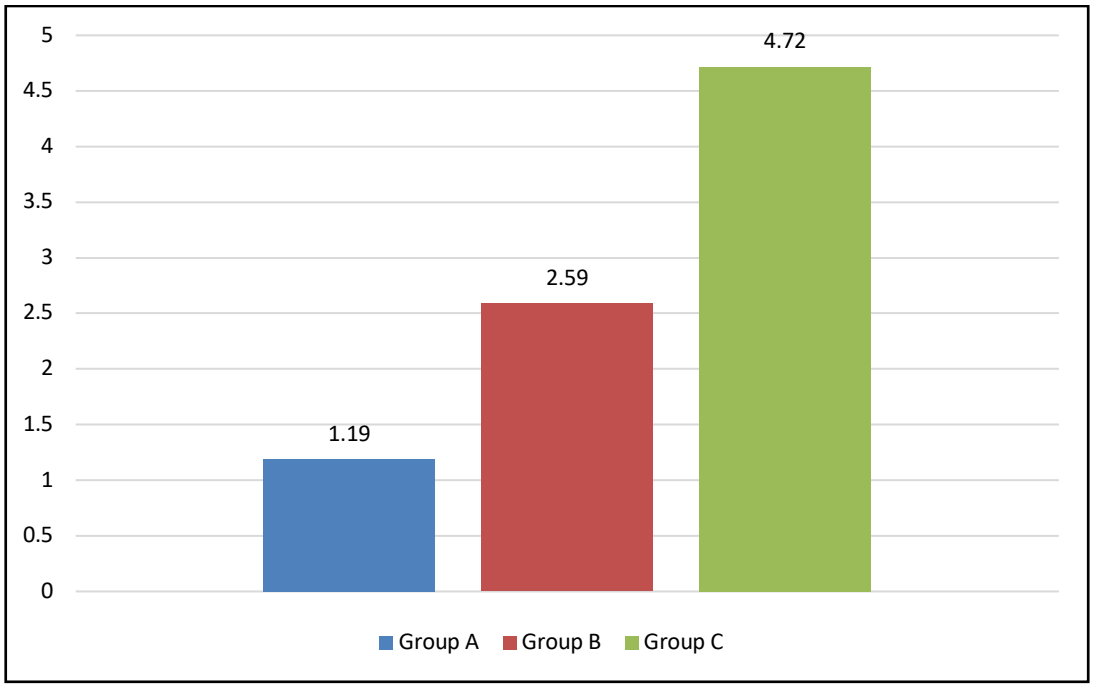
The mean FLACC scores recorded during the procedure for the three study groups **(Table 4)** were analysed using one-way ANOVA. Group A demonstrated the lowest mean score at $1.19 \pm 0.55$, followed by Group B at $2.59 \pm 0.66$, while Group C exhibited the highest mean score of $4.72 \pm 0.83$. The differences in mean scores among the groups were statistically significant ($p = 0.001$). Further pairwise comparisons revealed significant differences between all groups: Group A vs. Group B ($p = 0.001$), Group A vs. Group C ($p = 0.001$), and Group B vs. Group C ($p = 0.001$).

**Table 4: Mean FLACC score during treatment**

| **Groups** | **Mean** | **S.D.** | **F value** | **p-value** |
|---|---|---|---|---|
| **Group A** | 1.19 | 0.55 | 331.573 | 0.001 |
| **Group B** | 2.59 | 0.66 | | |
| **Group C** | 4.72 | 0.83 | | |
| | **Mean difference** | **Std. error** | **95% CI** | **p-value** |
| **Group A v/s B** | -1.41 | 0.14 | -1.74 -1.07 | 0.001 |
| **Group A v/s C** | -3.53 | 0.14 | -3.86 -3.19 | 0.001 |
| **Group B v/s C** | -2.12 | 0.14 | -2.45 -1.78 | 0.001 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at $p<0.05$

**Graph 1: Mean FLACC score during treatment**




**Anxiety Assessment- Vehnam's Anxiety Scale**

Prior to initiating treatment, anxiety levels across the three groups were evaluated using one-way ANOVA **(Table 5)**. The mean anxiety score for Group A was $0.34 \pm 0.56$, for Group B it was $0.66 \pm 0.63$, and for Group C it was $0.78 \pm 0.54$. The analysis revealed a statistically significant difference among the groups ($p = 0.0001$). Subsequent intergroup comparisons using the Post Hoc Bonferroni test indicated significant differences between Group A and Group B ($p = 0.019$), as well as between Group A and Group C ($p = 0.001$).

**Table 5: Mean Venham's Anxiety scale before treatment**

| Groups | Mean | S.D. | F value | p-value |
|---|---|---|---|---|
| **Group A** | 0.34 | 0.56 | 7.757 | 0.0001 |
| **Group B** | 0.66 | 0.63 | | |
| **Group C** | 0.78 | 0.54 | | |

| | Mean difference | Std. error | 95% CI (Upper-Lower) | p-value |
|---|---|---|---|---|
| **Group A v/s B** | -0.320 | 0.115 | -0.60 -0.04 | 0.019 |
| **Group A v/s C** | -0.440 | 0.115 | -0.72 -0.16 | 0.001 |
| **Group B v/s C** | -0.120 | 0.115 | -0.40 0.16 | 0.902 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at $p<0.05$

**Graph 2: Mean Venham's Anxiety scale before treatment**

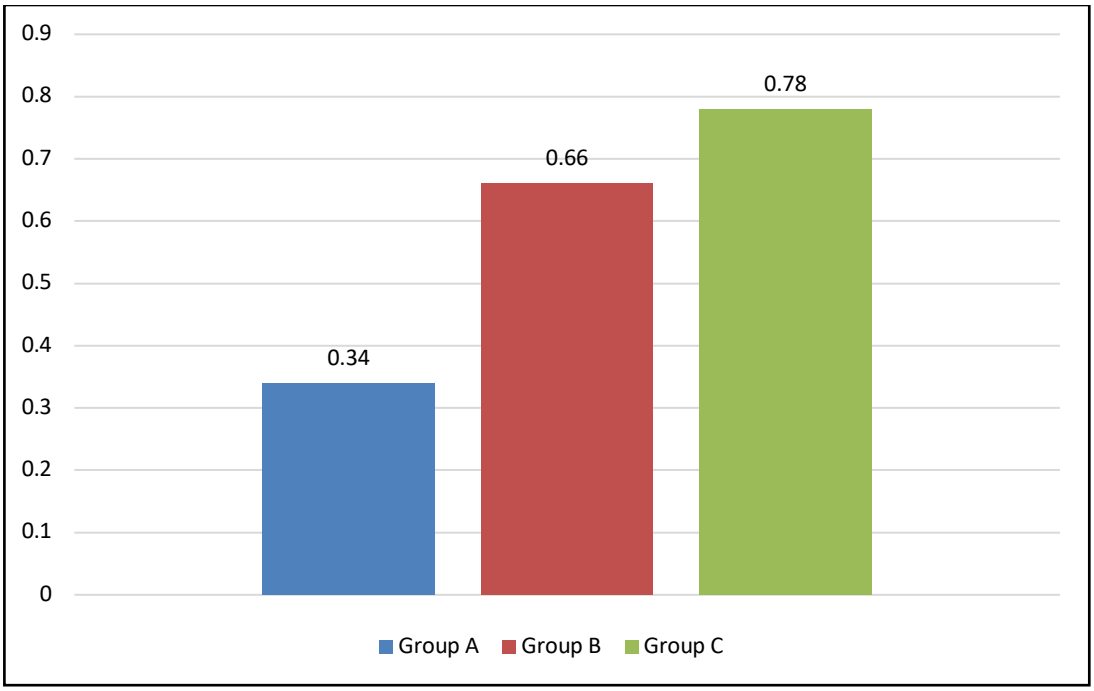



**Table 6** presents the mean anxiety scores during the procedure, assessed using Venham's anxiety scale. A one-way ANOVA was conducted to compare the anxiety levels among the three groups. Group A recorded the lowest mean anxiety score at $0.58 \pm 0.54$, followed by Group B at $1.90 \pm 0.84$, and Group C with the highest score of $2.32 \pm 0.91$. The differences among the groups were statistically significant ($p = 0.001$). Further analysis using the Post Hoc Bonferroni test revealed significant differences between all group pairs: Group A vs. Group B ($p = 0.001$), Group A vs. Group C ($p = 0.001$), and Group B vs. Group C ($p = 0.024$).

**Table 6: Mean Venham's anxiety scale during treatment**

| Groups | Mean | S.D. | F value | p-value |
|---|---|---|---|---|
| **Group A** | 0.58 | 0.54 | 67.657 | 0.001 |
| **Group B** | 1.90 | 0.84 | | |
| **Group C** | 2.32 | 0.91 | | |
| | **Mean difference** | **Std. error** | **95% CI** | **p-value** |
| **Group A v/s B** | -1.32 | 0.156 | -1.70 -0.94 | 0.001 |
| **Group A v/s C** | -1.74 | 0.156 | -2.12 -1.36 | 0.001 |
| **Group B v/s C** | -0.42 | 0.156 | -0.80 -0.04 | 0.024 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at $p<0.05$

**Graph 3: Mean Venham's anxiety scale during treatment**

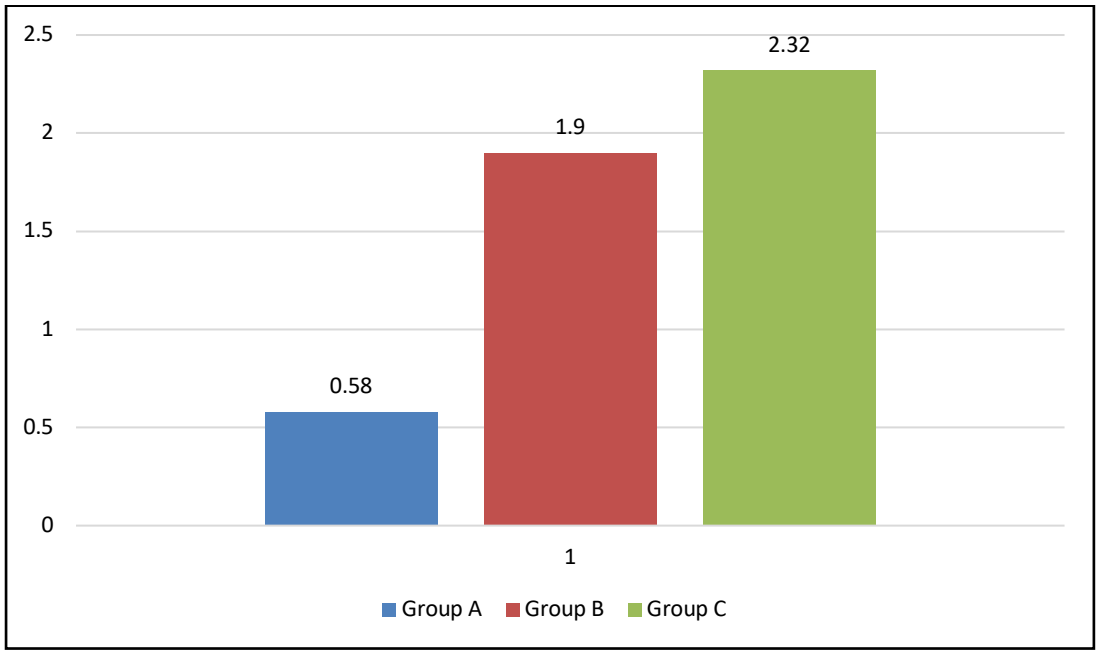


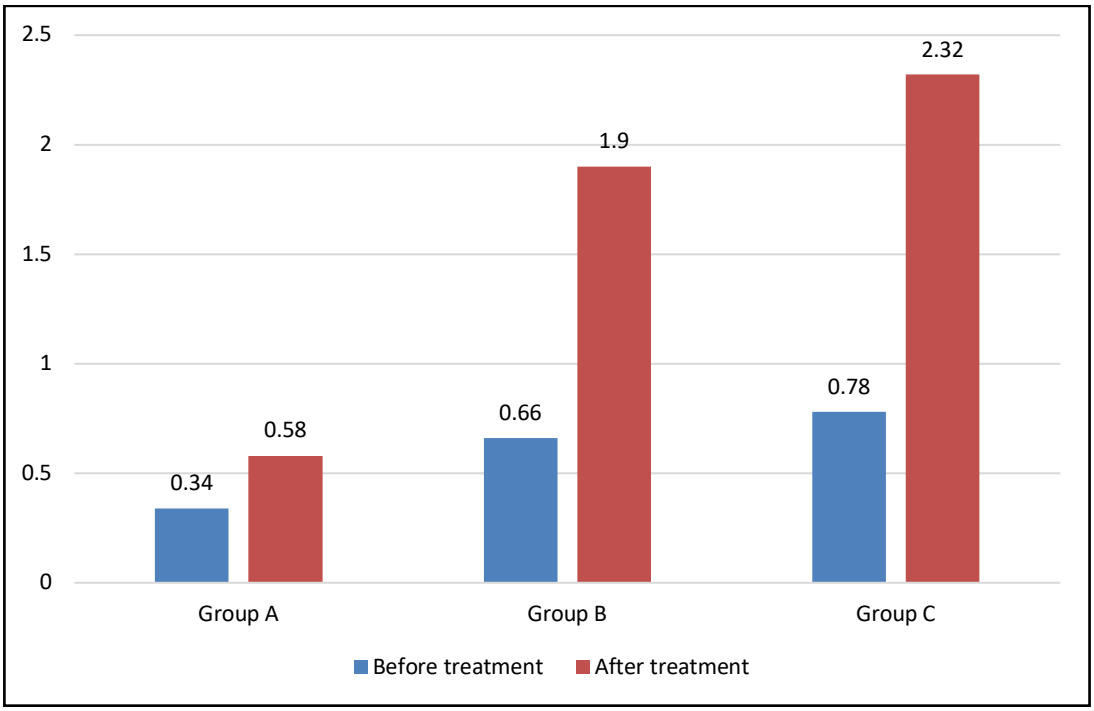
**Table 7** illustrates the mean change in anxiety levels across each group before and during treatment. All three groups exhibited an increase in mean anxiety levels during the treatment phase, with this increase being statistically significant for each group. Group C experienced the most substantial rise in mean anxiety, with a mean difference of 1.54, followed by Group B at 1.24. Group A showed the smallest increase, with a mean difference of 0.24.

**Table 7: Mean change in venham's anxiety levels before and during treatment**

| | Before treatment | | During treatment | | Mean diff. | p-value |
|---|---|---|---|---|---|---|
| **Groups** | **Mean** | **S.D.** | **Mean** | **S.D.** | | |
| **Group A** | 0.34 | 0.56 | 0.58 | 0.54 | -0.240 | 0.006 |
| **Group B** | 0.66 | 0.63 | 1.90 | 0.84 | -1.240 | 0.0001 |
| **Group C** | 0.78 | 0.54 | 2.32 | 0.91 | -1.540 | 0.001 |

Paired t- test applied, p-value significant at $p<0.05$

**Graph 4: Mean change in venham's anxiety levels before and during treatment**



**Pulse Rate Assessment- Pulse Oximeter**

**Table 8** presents the mean pulse rates prior to the commencement of treatment. The mean pulse rates across the three groups were compared using a one-way ANOVA. Group A had a mean pulse rate of 88.87 ± 4.66, Group B had 95.87 ± 4.66, and Group C had 101.73 ± 4.37. A statistically significant difference was observed among the groups (p = 0.0001). Post-hoc analysis using the Bonferroni test revealed significant differences between all pairwise group comparisons: Group A vs. Group B (p = 0.001), Group A vs. Group C (p = 0.001), and Group B vs. Group C (p = 0.001).

**Table 8: Mean Pulse rate before treatment**

| **Groups** | **Mean** | **S.D.** | **F value** | **p-value** |
|---|---|---|---|---|
| **Group A** | 88.87 | 4.66 | 99.118 | 0.0001 |
| **Group B** | 95.87 | 4.66 | | |
| **Group C** | 101.73 | 4.37 | | |
| | **Mean difference** | **Std. error** | **95% CI** | **p-value** |
| **Group A v/s B** | -7.00 | 0.91 | -9.21 -4.78 | 0.001 |
| **Group A v/s C** | -12.85 | 0.91 | -15.07 -10.64 | 0.001 |
| **Group B v/s C** | -5.85 | 0.91 | -8.07 -3.64 | 0.001 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at p<0.05

**Graph 5: Mean Pulse rate before treatment**

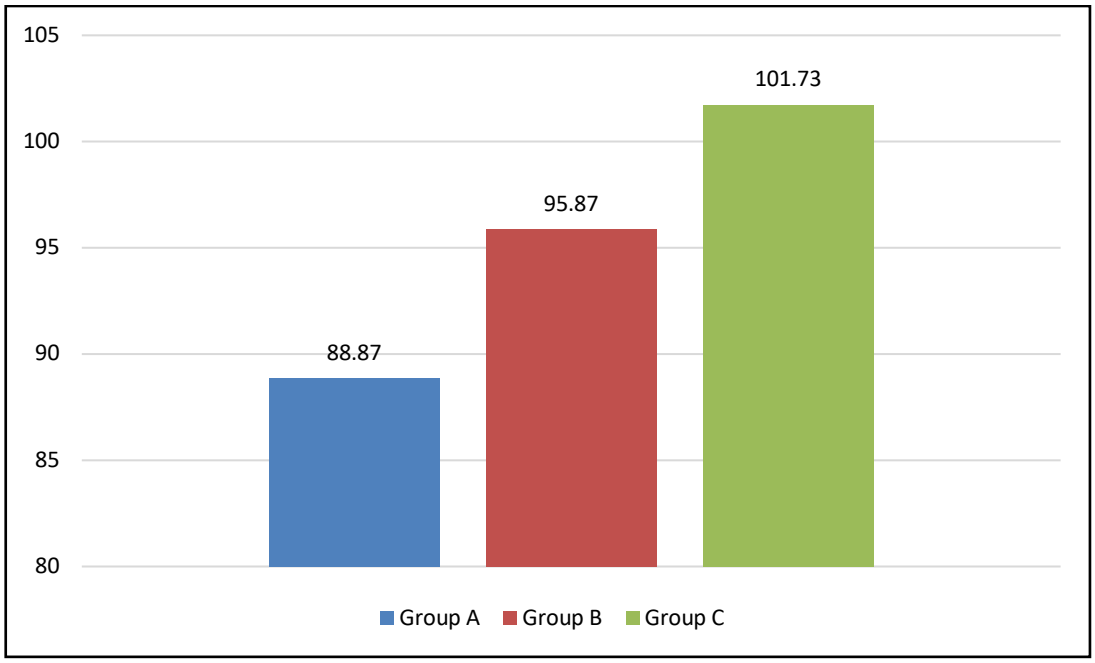



**Table 9** displays the mean pulse rates during the treatment phase. A one-way ANOVA was conducted to compare the mean pulse rates across the three groups. Group A had a mean pulse rate of 105.09 ± 4.37, Group B had 112.60 ± 5.07, and Group C had 114.62 ± 4.28. Group C exhibited the highest mean pulse rate, followed by Group B, and Group A showed the lowest mean pulse rate. A statistically significant difference was observed among the groups ($p = 0.001$). Post-hoc analysis using the Bonferroni test revealed significant differences between Group A and Group B ($p = 0.001$), Group A and Group C ($p = 0.001$), but no significant difference was found between Group B and Group C ($p = 0.089$).

**Table 9: Mean Pulse rate during treatment**

| **Groups** | **Mean** | **S.D.** | **F value** | **p-value** |
|---|---|---|---|---|
| **Group A** | 105.09 | 4.37 | 59.851 | 0.001 |
| **Group B** | 112.60 | 5.07 | | |
| **Group C** | 114.62 | 4.28 | | |

| | Mean difference | Std. error | 95% CI | p-value |
|---|---|---|---|---|
| **Group A v/s B** | -7.51 | 0.918 | -9.73 -5.29 | 0.001 |
| **Group A v/s C** | -9.53 | 0.918 | -11.75 -7.31 | 0.001 |
| **Group B v/s C** | -2.01 | 0.918 | -4.23 0.21 | 0.089 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at $p<0.05$

**Graph 6: Mean Pulse rate during treatment**

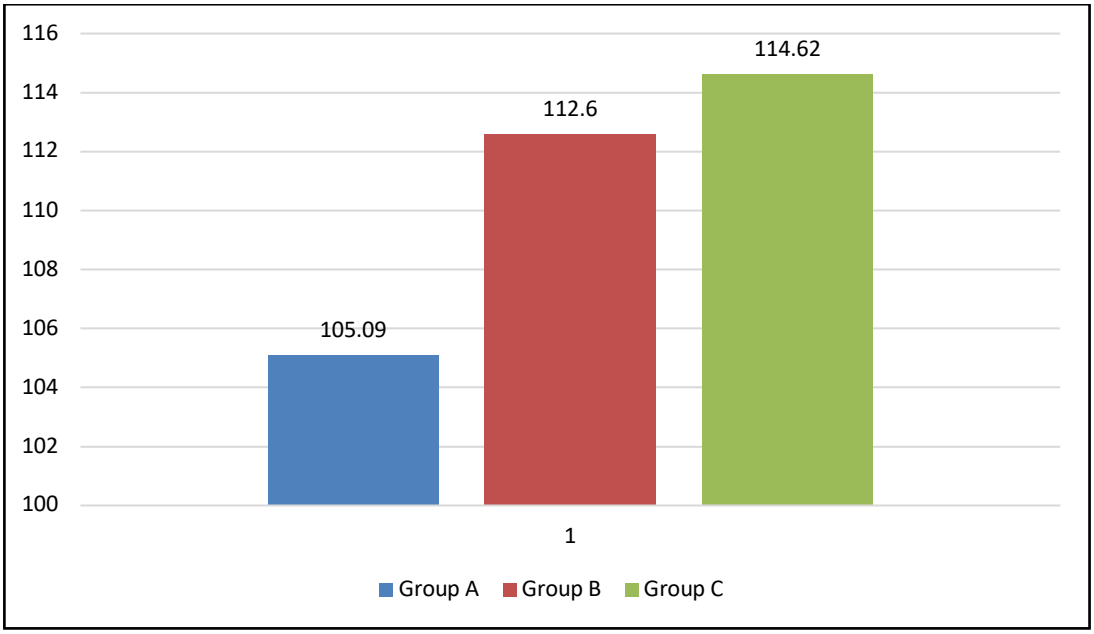


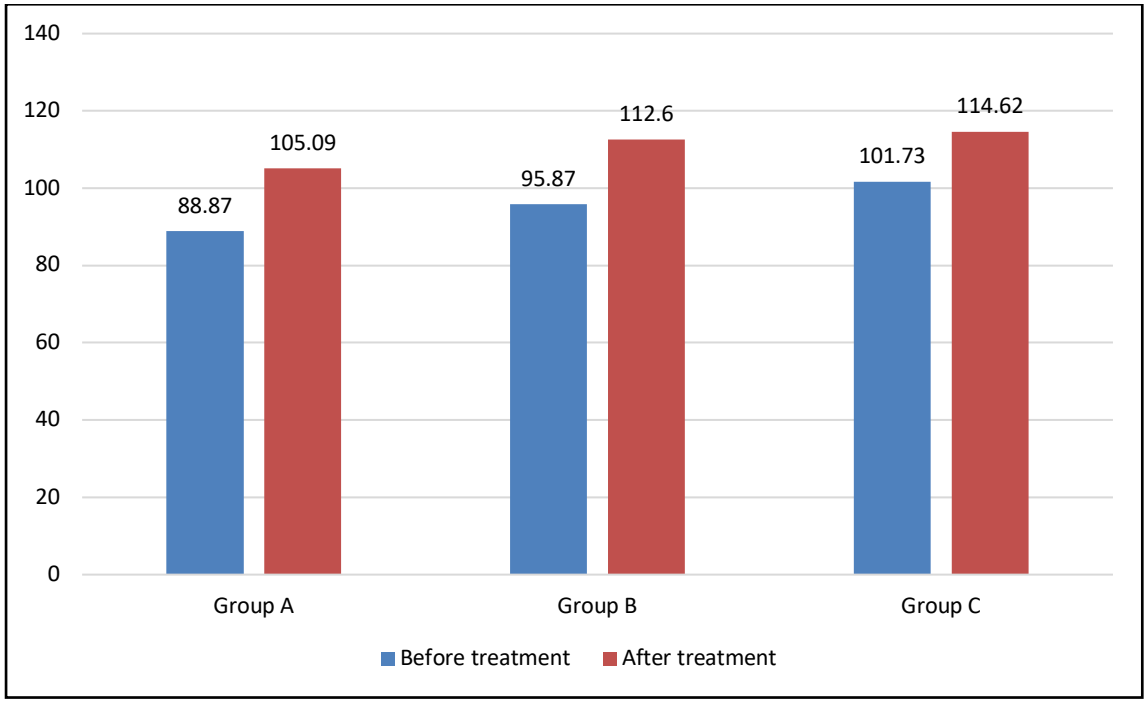

**Table 10** presents the mean change in pulse rate within each group before and during treatment. All three groups exhibited an increase in mean pulse rate during treatment, with this increase from baseline being statistically significant for each group. Group B experienced the largest rise in mean pulse rate, with a mean difference of 16.73, followed by Group A with a mean difference of 16.22. Group C showed the smallest increase in pulse rate, with a mean difference of 12.89.

**Table 10: Mean change in pulse rate before and during treatment**

| | Before treatment | | During treatment | | Mean Diff | p-value |
|---|---|---|---|---|---|---|
| **Groups** | **Mean** | **S.D.** | **Mean** | **S.D.** | | |
| **Group A** | 88.87 | 4.66 | 105.09 | 4.37 | -16.22 | 0.001 |
| **Group B** | 95.87 | 4.66 | 112.60 | 5.07 | -16.73 | 0.001 |
| **Group C** | 101.73 | 4.37 | 114.62 | 4.28 | -12.89 | 0.001 |

Paired t- test applied, p-value significant at $p<0.05$

**Graph 7: Mean change in pulse rate before and during treatment**



**Behaviour Assessment- Frankl Behaviour Rating Scale**

**Table 11** presents the mean Frankl behavior rating scores prior to the start of treatment. The mean values for Group A were 3.44 ± 0.50, for Group B 3.34 ± 0.47, and for Group C 3.58 ± 0.49. However, no statistically significant difference was found among the three groups (P = 0.053).

**Table 11: Mean Frankl Behaviour rating before treatment**

| Groups | Mean | S.D. | F value | p-value |
|---|---|---|---|---|
| **Group A** | 3.44 | 0.50 | 2.990 | 0.053 |
| **Group B** | 3.34 | 0.47 | | |
| **Group C** | 3.58 | 0.49 | | |

One-way ANOVA applied; p-value significant at p<0.05

**Graph 8: Mean Frankl Behaviour rating before treatment**

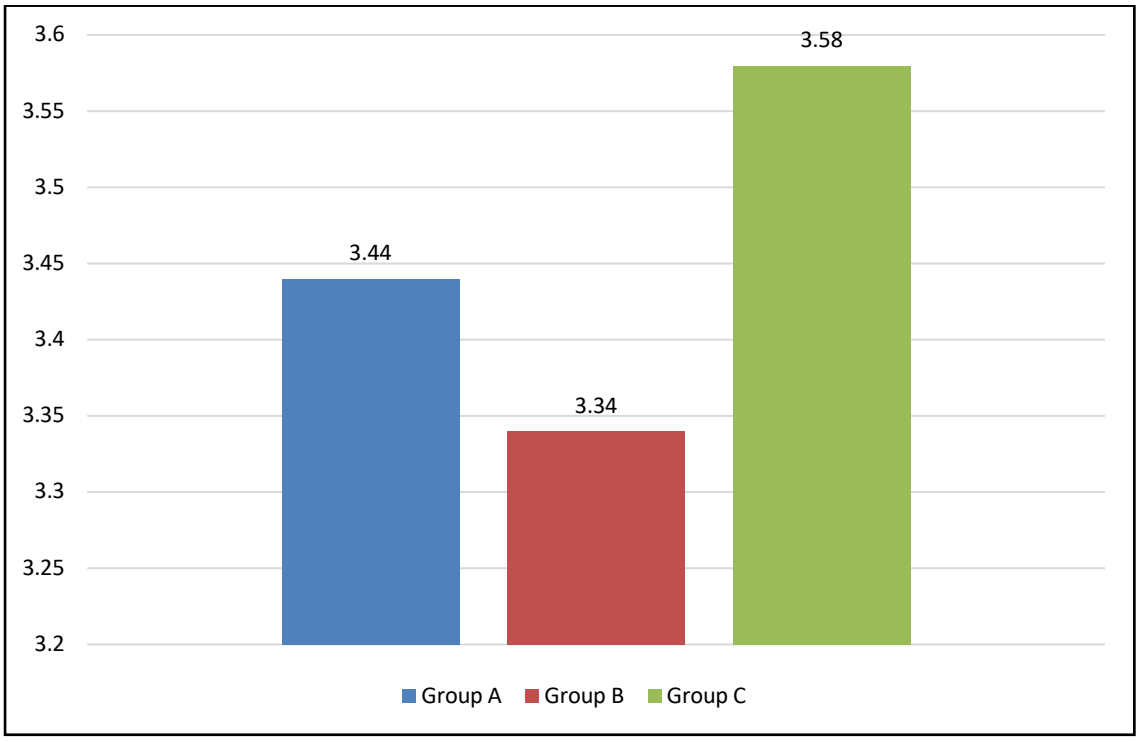


**Table 12** presents the mean Frankl behavior ratings for the three groups after treatment. A one-way ANOVA was used to compare the mean behavior ratings across the groups. Group A had a mean Frankl behavior rating of 3.20 ± 0.54, Group B had 2.74 ± 0.63, and Group C had 2.32 ± 0.71. Group A showed the highest mean rating, followed by Group B, with Group C having the lowest ratings. A statistically significant difference was observed among the groups (p = 0.001). Post-hoc analysis using the Bonferroni test revealed significant differences between all pairwise group comparisons: Group A vs. Group B (p = 0.001), Group A vs. Group C (p = 0.001), and Group B vs. Group C (p = 0.003).

**Table 12: Mean Frankl behaviour rating scale after treatment**

| **Groups** | **Mean** | **S.D.** | **F value** | **p-value** |
|---|---|---|---|---|
| **Group A** | 3.20 | 0.54 | 24.341 | 0.001 |
| **Group B** | 2.74 | 0.63 | | |
| **Group C** | 2.32 | 0.71 | | |
| | **Mean difference** | **Std. error** | **95% CI** | **p-value** |
| **Group A v/s B** | 0.460 | 0.126 | 0.15 0.77 | 0.001 |
| **Group A v/s C** | 0.880 | 0.126 | 0.57 1.19 | 0.001 |
| **Group B v/s C** | 0.420 | 0.126 | 0.11 0.73 | 0.003 |

One-way ANOVA, Post-hoc Bonferroni applied, p-value significant at p<0.05

**Graph 9: Mean Frankl behaviour rating scale after treatment**

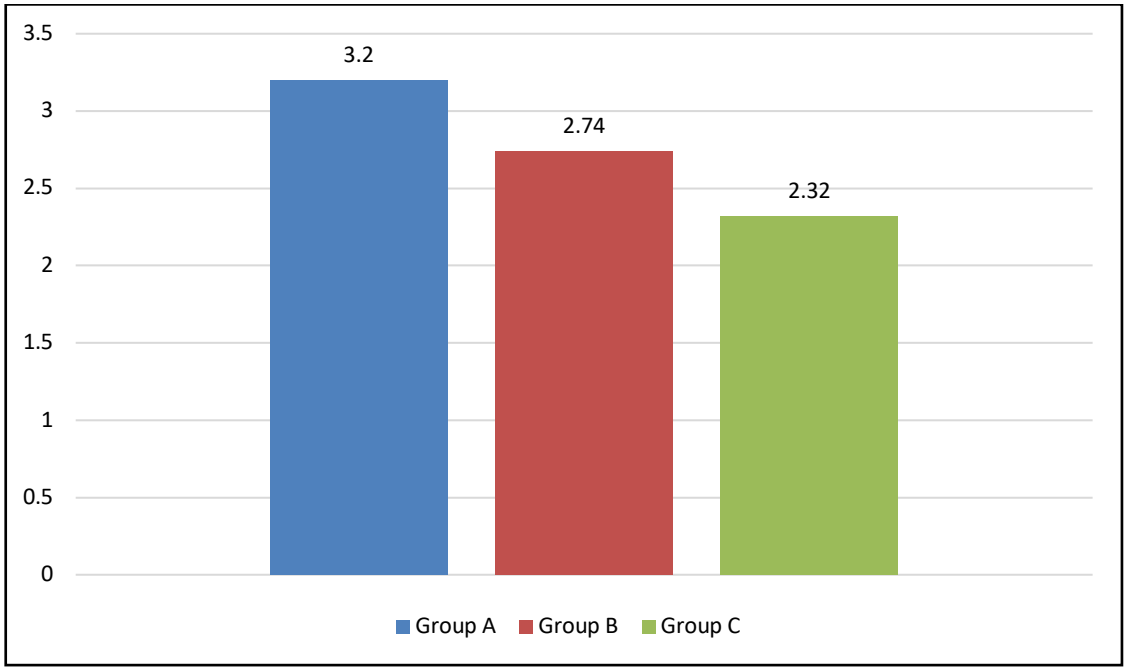


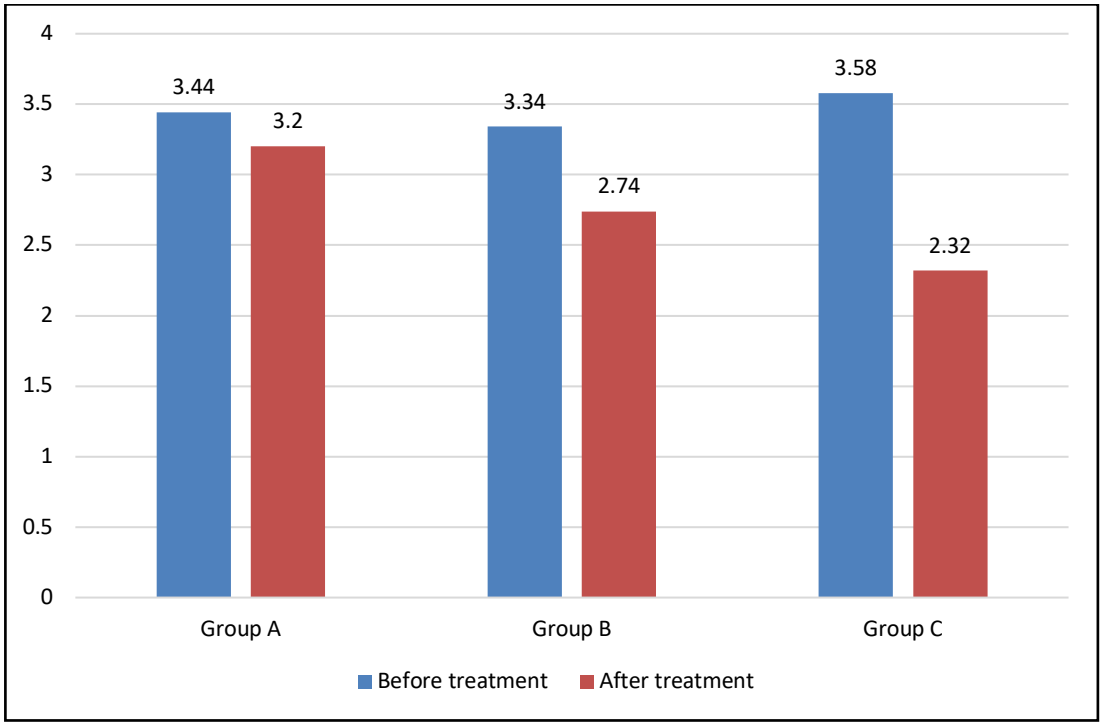

**Table 13** shows the mean change in Frankl behavior rating scores within each group before and after treatment. All three groups demonstrated a decrease in mean Frankl behavior ratings following treatment, and this reduction from baseline was significant for each group. Group C experienced the largest decrease in mean Frankl behavior ratings, with a mean difference of 1.26, followed by Group B with a mean difference of 0.60. Group A showed the smallest decrease, with a mean difference of 0.24.

**Table 13: Mean change in Frankl behaviour rating before and after treatment**

| | **Before treatment** | | **After treatment** | | **Mean diff.** | **p-value** |
|---|---|---|---|---|---|---|
| **Groups** | **Mean** | **S.D.** | **Mean** | **S.D.** | | |
| **Group A** | 3.44 | 0.50 | 3.20 | 0.54 | 0.240 | 0.017 |
| **Group B** | 3.34 | 0.47 | 2.74 | 0.63 | 0.600 | 0.001 |
| **Group C** | 3.58 | 0.49 | 2.32 | 0.71 | 1.260 | 0.001 |

Paired t- test applied, p-value significant at $p<0.05$

**Graph 10: Mean change in Frankl behaviour rating before and after treatment**


4
3.5
3
2.5
2
1.5
1
0.5
0
3.44
3.2
3.34
2.74
3.58
2.32
Group A
Group B
Group C
Before treatment
After treatment

# DISCUSSION

According to the International Association for the Study of Pain, pain is characterized as "an unpleasant sensory and emotional experience that is linked to actual or potential tissue damage, or is expressed in relation to such damage".[3] Inadequate pain management in children can evoke negative responses and fears, posing significant barriers for dentists aiming to establish trust and positive attitudes in their paediatric patients. Effective pain management fosters trust, alleviates fear, and promotes a favourable dental experience.[4]

Local anesthesia, a cornerstone of pain control in pediatric dental care, is defined by Malamed as the temporary and reversible loss of sensation in a targeted area, achieved either by suppressing nerve excitation at the sensory terminals or by blocking impulse transmission along peripheral nerves. Local anaesthetics act by blocking the rapid sodium ion influx required for neuron impulse propagation, thereby preventing pain during procedures.[5] These agents not only minimize pain but also contribute to building trust between the dentist and patient thereby, reducing fear and anxiety, and encouraging positive attitudes toward future dental visits.[6]

Children experiencing heightened dental anxiety often report exaggerated perceptions of pain, which prolong discomfort and instil negative memories of dental visits. This dual-edged nature of pain in dentistry—as both a motivator for seeking care and a deterrent due to fear—highlights the importance of managing emotional and physiological aspects of pain simultaneously. Addressing these challenges is crucial for fostering positive attitudes toward dental care in young patients.[2]

The delivery of local anesthesia has undergone significant advancements, revolutionizing its application in modern dentistry. The invention of the hypodermic syringe by Alexander Wood in 1853 marked a pivotal moment, enabling the precise delivery of injectable anesthesia and transforming pain management.[7]

Devices like VibraJect and DentalVibe are designed to mitigate injection-related discomfort by leveraging the gate control theory of pain modulation. This theory, originally proposed by Melzack and Wall in 1965, suggests that non-noxious stimuli—such as vibration—can inhibit the transmission of pain signals by activating large-diameter afferent nerve fibers, thereby "closing the gate" to nociceptive input at the spinal cord level.[8–10] The VibraJect system (Miltex Inc., York, PA) is a compact, battery-operated device engineered to deliver high-frequency vibrations during the administration of local anesthesia. It attaches directly to a standard dental syringe and transmits vibration along the needle, thereby diminishing pain perception during injection.[16]

Among the latest innovations, the Starpen device **(**Guilin Woodpecker Medical Instrument Co., Ltd.) represents a significant advancement in painless anaesthesia delivery. It is an electronic dental anaesthesia (EDA) system, combining artificial intelligence algorithms with pressure feedback technology, which offers precise control over injection speed and pressure, enhancing patient comfort. The device offers three different adjustable speeds—high, low, and hybrid—with two aspiration modes—manual and auto, resulting in a more pleasant experience for the patient.

This randomized controlled trial evaluated behavioral responses, anxiety levels, pulse rate, and pain perception in pediatric patients undergoing local anesthesia with StarPen, Vibraject, and conventional syringes. The procedure involved administering an Inferior Alveolar Nerve Block using each of the three delivery systems. During the injection, the child's pain, anxiety, and physiological response were assessed using the FLACC Scale (Face, Legs, Activity, Cry, Consolability), Venham's Anxiety Scale, and pulse oximetry, respectively. Immediately following the injection, behavioral response was re-evaluated using the Frankl Behavior Rating Scale. All data were systematically recorded using a pre-designed proforma.

All observations and records were documented systematically in a pre-structured proforma.
Statistical analysis was conducted using one-way Analysis of Variance (ANOVA) to compare the mean scores of behavioral response, anxiety levels, pulse rate, and pain perception across the three

intervention groups—StarPen, VibraJect, and conventional syringe. When a statistically significant difference was identified ($p < 0.05$), post-hoc pairwise comparisons were performed using the Bonferroni correction to control for Type I error and to determine which specific groups differed from each other. A p-value of less than 0.05 was considered indicative of statistical significance.

Before starting the treatment, the anxiety levels among the three groups were compared using one-way ANOVA. Group A had a mean anxiety level of 0.34+0.56, Group B was 0.66+0.63 and Group C was 0.78+0.54. There was statistically significant difference among the three groups (p=0.0001). The StarPen, which likely employs a more controlled, less invasive technique for local anesthesia administration, may result in a reduced perception of pain or discomfort, leading to a lower level of anxiety in the children in Group A (StarPen). On the other hand, Vibraject and the conventional syringe (which might involve more direct and possibly more painful injection techniques) could increase the child's anxiety levels due to the anticipation or actual experience of discomfort during the procedure.

A study by Kakodkar et al. (2020) [(69)] on pediatric dental anxiety and pain perception supports this idea, where they found that less painful or less stressful techniques (like the use of a mechanical injector or a more controlled delivery of local anesthesia) resulted in reduced anxiety levels compared to traditional methods. This aligns with the findings in the current study, where StarPen (as a potentially less painful technique) resulted in significantly lower anxiety compared to the Vibraject and conventional syringe groups.

Both StarPen and Vibraject devices incorporate mechanisms that reduce the discomfort associated with needle injections. The Vibraject device, which uses a vibratory stimulus during the injection, has been shown to distract children from the pain and reduce their anxiety. This mechanism might help explain why Group B (Vibraject) showed a somewhat higher anxiety level compared to Group A (StarPen) but still lower than the conventional syringe group.

Research by Al-Muwallad et al. (2018) [70] also supports this, indicating that devices like Vibraject help decrease the pain perception and anxiety in pediatric patients. Although Vibraject may not reduce pain perception as dramatically as StarPen, it still provides a more comfortable experience than conventional injection methods.

Venham et al.(1979) developed and evaluated the 6-point Cooperative Behavioral Scale, also known as the Uncooperative Behavior Rating Scale [71], which provides a comprehensive assessment of a child's behavior during dental visits. This scale categorizes behavior into six distinct levels, with each point corresponding to observable and specific actions. The dentist assesses the child's behavior by selecting a number from 0 to 5, based on the scale, either after the dental visit or at predetermined points throughout the procedure. The study also utilized the Venham Anxiety Scale, which measures anxiety through the child's physiological responses and behavior. Children are often sensitive to their environment and may show less anxiety when exposed to less distressing procedures or more familiar instruments, such as the StarPen. This could help explain why the StarPen group (Group A) recorded the lowest anxiety scores in the study.

According to a study by Ayyad et al. (2014) [72], factors like the type of needle or syringe, and the child's previous experiences with dental care can significantly impact their anxiety levels. This aligns with the lower anxiety level observed in Group A, as they may have had a more positive experience with StarPen on the first visit, reducing their anticipatory anxiety for future visits.

The anxiety levels at baseline (before treatment) might also be influenced by the child's prior experiences or expectations. If the child had a painful or distressing experience with a conventional syringe previously, they may have a heightened level of anxiety before the procedure starts, as observed in Group C (conventional syringe). Treadwell et al. (2017) [73] highlighted the role of past dental experiences and expectations in influencing a child's pre-treatment anxiety.

The FLACC scale was employed as an objective measure to assess pain levels during local anesthetic administration. This validated observational tool evaluates five behavioral components: facial expression, leg movement, activity level, crying, and consolability. Each category is scored

from 0 to 2, resulting in a total pain score ranging from 0 (no pain) to 10 (severe pain). A reduction in FLACC score corresponds to a decrease in pain perception, whereas higher values indicate increased pain intensity. This scale has been widely utilized in pediatric settings for its reliability in assessing procedural pain.[68]

The mean FLACC scores among the three groups were compared using one-way ANOVA. Group A had a mean FLACC score of 1.19±0.55, Group B was 2.59±0.66 and Group C was 4.72±0.83. The mean FLACC score was highest in Group C followed by Group B and least in Group A. There was statistically significant difference among the three groups (p=0.001). Intergroup comparisons were then analyzed using Post hoc Bonferroni test which showed statistically significant differences among all the three groups i.e. between Group A and B (p=0.001), Group A and C (p=0.001) and Group B and C (p=0.001).

The statistically significant differences in the mean anxiety scores among the three groups (Group A: StarPen, Group B: Vibraject, and Group C: conventional syringe) are likely attributable to the varying experiences and comfort levels provided by each local anesthesia technique. These results suggest that the method of local anesthesia delivery significantly influences the anxiety levels in children undergoing dental procedures. This could be attributed to the fact that The StarPen likely provided a more comfortable and less intimidating experience for the children in Group A, which could explain the lowest mean anxiety score (0.58+0.54). The StarPen is designed to reduce pain and discomfort through a controlled and less invasive delivery system, which has been shown to improve patient comfort and reduce anxiety during local anesthesia administration.

Research by Al-Muwallad et al. (2018) [70] and Kakodkar et al. (2020) [69] supports the notion that less painful or more precise methods of delivering local anesthesia tend to result in lower anxiety levels in children. These studies highlight how devices like the StarPen, which minimize needle penetration and discomfort, contribute to a more positive experience, leading to reduced anxiety.

Vibraject uses vibration during the injection process, which has been shown to distract patients from the pain and reduce their overall perception of discomfort. While it was more effective than

the conventional syringe (Group C), it still resulted in higher anxiety levels (mean score of 1.90+0.84) compared to StarPen.

Although Vibraject reduces pain perception, it may not be as effective as the StarPen in alleviating anxiety, as it still involves a needle-based injection. The vibration can mitigate the sensation of pain but may not reduce the psychological stress associated with injections entirely.

Al-Muwallad et al. (2018) [70] noted that while devices like Vibraject help reduce pain, the need for a needle still contributes to a certain level of anxiety, as the anticipation of the injection can be distressing for children.

The conventional syringe method resulted in the highest mean anxiety score (2.32+0.91). This method, being the most traditional, is often associated with greater discomfort and fear due to the visual and tactile cues of the needle. Additionally, children who are not accustomed to dental procedures may have heightened anxiety based on previous negative experiences or general fear of needles.

Treadwell et al. (2017) [73] emphasized that children's anxiety is often influenced by prior dental experiences and the perceived invasiveness of the procedure. Conventional syringe injections, with their more invasive nature and the visible presence of needles, likely contribute to a greater sense of fear and anxiety in children.

These findings align with research from Kakodkar et al. (2020) [69], who demonstrated that newer, less invasive devices significantly reduce pediatric dental anxiety when compared to traditional methods. The difference in anxiety scores among the groups reflects the effectiveness of these newer devices (StarPen and Vibraject) in providing a less stressful experience. The lowest anxiety levels in Group A (StarPen) are likely due to the controlled, less invasive nature of the injection, which reduces both physical discomfort and psychological stress. Group B (Vibraject) showed moderate anxiety, likely because although it reduces pain perception through vibration, it still involves needle-based injection, which can cause anxiety in children. Group C (conventional syringe) had the highest anxiety scores, consistent with the well-documented association between traditional needle injections and higher levels of pediatric anxiety.

These results support the conclusions of studies by Al-Muwallad et al. (2018) [70] and Kakodkar et al. (2020) [69], which highlight the importance of minimizing pain and discomfort to reduce dental anxiety, particularly in pediatric patients.

The statistically significant differences in pulse rate among the three groups (Group A: StarPen, Group B: Vibraject, and Group C: conventional syringe) can be interpreted by understanding how physiological responses, such as pulse rate, correlate with the stress and anxiety associated with each anesthesia technique during dental procedures.

The children in Group A (StarPen) had the lowest mean pulse rate (105.09 ± 4.37). This is likely because the StarPen device delivers a more controlled and less invasive injection, causing less pain and psychological stress during the procedure. Lower levels of anxiety and discomfort generally result in fewer physiological signs of distress, such as increased heart rate.

Studies have shown that less painful methods of local anesthesia, such as those using the StarPen, tend to reduce both the perception of pain and physiological indicators of stress, such as pulse rate. Kakodkar et al. (2020) [69] and Al-Muwallad et al. (2018) [70] found that less painful and less invasive devices typically lead to fewer physiological responses like elevated heart rate.

The highest pulse rate in Group C (conventional syringe) aligns with the known impact of traditional needle injections, which cause more discomfort and anxiety, leading to a greater physiological stress response. These findings are supported by studies such as Kakodkar et al. (2020) [69] and Al-Muwallad et al. (2018) [70], which found that less invasive and less painful injection techniques lead to lower anxiety and lower heart rates in children. The Treadwell et al.(2017) [73] study also corroborates that needle-based methods elevate heart rate due to stress and pain perception.

The Frankl Behavior Rating Scale (FBRS), as adapted by Wright, was used to evaluate pediatric patient behavior during various stages of the dental procedure. This widely accepted scale categorizes behavior into four distinct levels, ranging from definitively negative to definitively positive responses. Behavioral assessment was conducted at key procedural stages, including extraoral and intraoral examination, radiographic imaging.[66] Table 13 represents the mean change

in Frankl behaviour rating scores within each group before and after treatment. All the three groups showed that the mean Frankl behaviour rating scores decreased after treatment and this decrease from baseline was significant for all the three groups. Group C had the highest decrease in mean Frankl behaviour rating scores with a mean difference of 1.260 followed by Group B with a mean difference of 0.60 and Group A had least decrease in Frankl behaviour rating scores with a mean difference of 0.240.

Group C (conventional syringe) showed the highest decrease in Frankl behavior rating scores with a mean difference of 1.260. This suggests that children in this group experienced the most negative behavioral response during the procedure, likely due to the pain and anxiety associated with the traditional needle injection.

Traditional syringe-based injections are often associated with higher pain perception and greater anxiety, especially in children who may have had negative previous experiences or have a general fear of needles. This increased discomfort likely led to more negative behavior, such as crying, resistance, or fear, resulting in a greater decrease in the Frankl score.

This result is consistent with findings from Treadwell et al. (2017) and Kakodkar et al. (2020), who noted that conventional needle injections often provoke more distress and negative behaviors in pediatric patients due to the invasive nature of the procedure and the pain it can cause.

Group B (Vibraject) showed a moderate decrease in Frankl behavior rating scores (mean difference of 0.60). Vibraject, which uses vibration to reduce pain perception during injection, may have helped to alleviate some discomfort, but it still involves a needle, which likely caused a moderate degree of anxiety and discomfort in the children.

Although Vibraject has been shown to reduce pain perception, it does not completely eliminate the psychological stress associated with injections, as children may still anticipate discomfort. Therefore, the decrease in behavior scores in Group B was less than that observed in Group C, but still noticeable.

Research by Al-Muwallad et al. (2018) [70] supports the idea that while Vibraject can reduce pain, it may not fully mitigate anxiety, which could explain why the behavior rating scores in Group B were lower than Group A but higher than Group C.

Group A (StarPen) showed the least decrease in Frankl behavior rating scores, with a mean difference of 0.240. This suggests that children in Group A had the least negative behavioral response, likely because the StarPen provides a more controlled, less painful injection experience. The StarPen's technology likely minimizes discomfort during the procedure, leading to less anxiety, pain, and fear. As a result, children in this group were likely to remain calmer and exhibit fewer signs of distress during treatment, reflected by the smallest decrease in behavior ratings.

Within the confinement of this study, it was concluded that the study demonstrates that the method of local anesthesia administration significantly impacts pediatric patients' anxiety, behavior, and physiological responses, with StarPen providing the most favorable outcomes in terms of reducing anxiety, improving behavior, and minimizing physiological stress compared to Vibraject and conventional syringe techniques.

# SUMMARY AND CONCLUSION

Effective pain management is critical in pediatric dentistry to enhance patient cooperation and reduce dental anxiety. This randomized controlled trial compared the effectiveness of two advanced local anesthesia delivery systems—StarPen and Vibraject—against conventional syringes in pediatric patients. The study included 150 children aged 6 to 10 years, randomized into three equal groups (n=50). Pain perception, anxiety, behavioral responses, and physiological indicators such as pulse rate were assessed using standardized and validated tools, including the Frankl Behavior Rating Scale, Venham Anxiety Scale, and FLACC Scale, in conjunction with pulse oximeter monitoring.

The results demonstrated that both StarPen and Vibraject significantly reduced pain perception and anxiety levels compared to conventional syringes. StarPen, with its computer-controlled delivery system, provided greater precision, enhanced patient comfort, and lower physiological stress, resulting in statistically superior pain and anxiety control. Vibraject, utilizing vibratory stimulation, also effectively masked pain perception but was slightly less effective than StarPen.

The outcomes of this study underscore the clinical relevance of adopting advanced local anesthesia delivery systems in pediatric dental practice. Among the techniques evaluated, StarPen proved to be the most effective, showing statistically significant reductions in pain perception, anxiety levels, and physiological stress markers, thereby presenting a compelling alternative to conventional syringe-based methods. Its precision-driven anesthetic administration reduces injection discomfort and enhances procedural acceptance in young patients, offering a valuable tool for pediatric pain management.

Vibraject also provided considerable pain relief and anxiety reduction, though its efficacy was slightly lower than StarPen. As a vibratory-assisted system, it remains a viable alternative to conventional syringes, particularly for children with mild to moderate dental anxiety. While both devices outperformed the traditional syringe, the computer-assisted StarPen system appears to

offer the greatest benefits in terms of pain minimization, behavioral adaptation, and improved physiological stability during local anesthesia administration.

The integration of advanced, patient-friendly anesthesia technologies has the potential to transform pediatric dental care by enhancing patient compliance, fostering positive dental experiences, and reducing long-term dental anxiety. These innovations may help mitigate the widespread fear of dental injections, ultimately improving oral health outcomes and promoting routine dental visits among pediatric patients.

# LIMITATION OF THE STUDY

While this study offers meaningful insights into the comparative effectiveness of StarPen and Vibraject in reducing pain perception and managing behavioral responses in pediatric patients, certain limitations must be acknowledged:

1. Sample Size and Generalizability – Despite enrolling 150 participants, the relatively limited sample size may constrain the broader applicability of the results. Future studies with larger cohorts are warranted to enhance the generalizability of the findings.
2. Short-Term Follow-Up- The study focused on immediate pain perception and anxiety levels. A longitudinal follow-up assessing the long-term impact on dental fear and compliance would provide more comprehensive insights.
3. Subjective Nature of Pain and Anxiety Assessment- While validated scales were used, pain and anxiety are inherently subjective experiences. Individual variations in pain tolerance and anxiety levels may influence the results.
4. Cost and Accessibility of Advanced Devices-While StarPen and Vibraject proved clinically effective, their cost-effectiveness and accessibility in various healthcare settings, including low-resource environments, remain unaddressed.

Addressing these limitations will lead to a more comprehensive understanding of advanced anesthesia delivery systems, ultimately enhancing pediatric dental care and optimizing patient experiences.

# SCOPE OF THE STUDY

To the best of our knowledge, this study represents a pioneering effort in evaluating the efficacy of StarPen for pain management, anxiety reduction, and behavioral response in pediatric dental anesthesia.

1. It holds potential for clinical innovation and could serve as a foundation for broader implementation in pediatric dentistry.
2. The findings from this research may further contribute to advancements in pain management strategies, extending beyond dental procedures to other medical applications requiring precise and anxiety-free local anesthesia delivery in children.

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# ANNEXURES

## ANNEXURE I

**SANTOSH**
**Deemed to be University**
(Established u/s 3 of the UGC Act, 1956)

F. No. SU/2023/2480[11] Dated: 26.09.2023

Subject: Grant of Ethical Clearance for Thesis Protocol Topic "Comparative Evaluation of Behavior, Anxiety, Pulse Rate and Pain Perception in Children Using Two Local Anesthesia Delivery Systems- A Randomized Controlled Trial", submitted by **Dr. SONAM YADAV,** MDS student of Batch 2022-2023, Department of **PEADIATRIC & PREVENTIVE DENTISTRY**.

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled "Comparative Evaluation of Behavior, Anxiety, Pulse Rate and Pain Perception in Children Using Two Local Anesthesia Delivery Systems- A Randomized Controlled Trial", **Dr. SONAM YADAV** is informed that the Thesis Protocol submitted by him/her was considered by the **Screening Committee** of the Santosh Dental College & Hospital in its meetings held on 07.02.2023 & 08.02.2023. The recommendations of the **Screening Committee** were considered in detail by the Institutional **Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee**.

He /She is informed accordingly for further necessary action.

[DR. NARESH SHARMA]
REGISTRAR

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, NCR DELHI

**Dr. SONAM YADAV**
MDS student of batch 2022-2023
Department of PEADIATRIC & PREVENTIVE DENTISTRY
Email: ydvsonam112@gmail.com

**Copy to:**
1. The Vice Chancellor
2. The Dean, SDC&H
3. The Dean – Research
4. The Dean – Academics
5. The Director - IQAC
6. **Dr. Natasha Gambhir** (Guide)
7. HOD of **PEADIATRIC & PREVENTIVE DENTISTRY**

## ANNEXURE II

## INFORMED CONSENT

**DEPARTMENT OF PEDIATRIC AND**

**PREVENTVE DENTISTRYSANTOSH DENTAL**

**COLLEGE AND HOSPITAL, GHAZIABAD**

I, Mr. / Mrs.…… F/O, M/O.……

Resident of ……

have been informed about all the benefits and risks during and after my child's dental procedure.

I am willingly for my child to participate in the study conducted by the department of Pediatric and Preventive Dentistry, Santosh Dental College and Hospital.

I should choose to withdraw my child from this study at any point; I will be free to do so after giving prior information to the concerned doctor.

Signature of Doctor In-charge
Date:

Signature of Parent
Date:

## ANNEXURE III

# संतोष डेंटल कॉलेज

### सूचित सहमति पत्र

### बाल एवं निवारक दंत चिकित्सा विभाग

मैं, श्री / श्रीमती .....पिता / माता .....

निवासी .....को मेरे बच्चे

की दंत चिकित्सा प्रक्रिया के दौरान और बाद में होने वाले सभी लाभों और जोखिमों की जानकारी दी गई है।

मैं अपनी स्वेच्छा से अपने बच्चे को संतोष डेंटल कॉलेज और अस्पताल, गाज़ियाबाद के बाल एवं निवारक दंत चिकित्सा विभाग द्वारा संचालित अध्ययन में भाग लेने के लिए अनुमति देता/देती हूँ।

यदि मैं कभी भी अपने बच्चे को इस अध्ययन से बाहर निकालना चाहूँ, तो मैं संबंधित चिकित्सक को पूर्व सूचना देकर ऐसा करने के लिए स्वतंत्र हूँ।

**प्रभारी चिकित्सक के हस्ताक्षर:** _____
**दिनांक:** _____

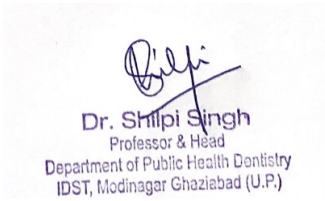
**अभिभावक के हस्ताक्षर:** _____
**दिनांक:** _____

# ANNEXURE IV

# STATISTICIAN CERTIFICATE

## TO WHOMSOEVER IT MAY CONCERN

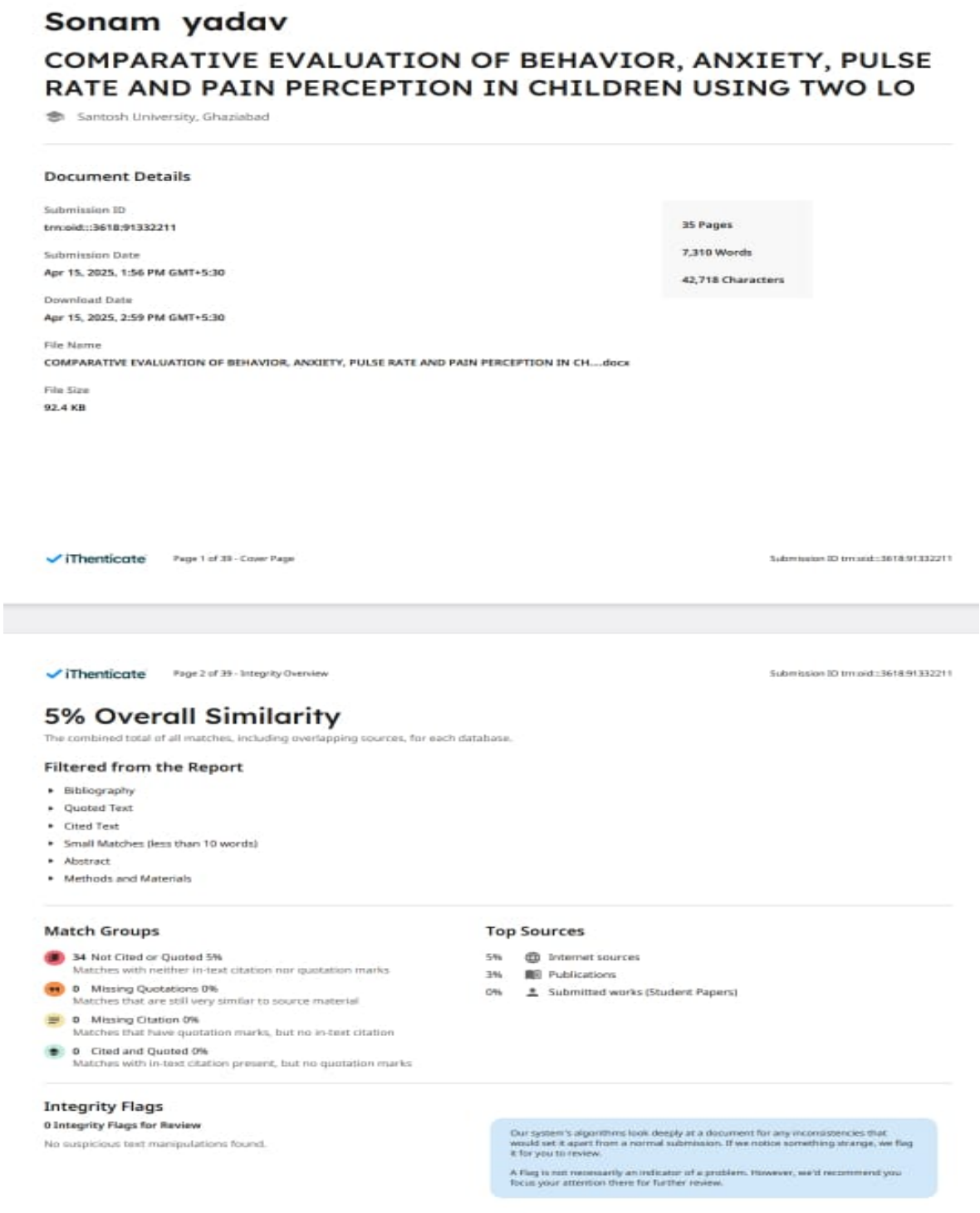
This is to certify that I have carried out the statistical analysis of the dissertation conducted by Dr. Sonam Yadav, Dept. of Pediatric and Preventive Dentistry, Santosh Dental College and Hospital titled "**Comparative Evaluation of Behaviour, Anxiety, Pulse Rate, and Pain Perception in Children Using Two Local Anaesthesia Delivery Systems: A Randomised Controlled Trial"**. The statistical analysis was done using SPSS version 30.0. Mean and standard deviation was compared using one way ANOVA followed by post hoc Bonferroni. Intragroup comparisons were done using Paired t-test. The p-value was significant at $p<0.05$. The results are authenticated to the best of my knowledge and belief.




**Dr. Shilpi Singh**
BDS, MDS
Professor & Head
Department of Public Health Dentistry
Institute of Dental Studies & Technologies,
Modinagar

# ANNEXURE V

# ANTI PLAGIARISM REPORT



Sonam yadav

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